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**COUNCIL**

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August 13, 2020

**SUBMITTED VIA EMAIL AND  
DNREC ONLINE PORTAL**

Department of Natural Resources and Environmental Control  
Attn: Lisa Vest  
Hearing Officer  
The Richardson & Robbins Building  
89 Kings Highway, Dover, DE 19901  
lisa.vest@delaware.gov  
DNRECHearingComments@delaware.gov  
<https://dnrec.alpha.delaware.gov/public-hearings/comment-form/>

**RE: Supplemental submission regarding Application of Croda, Inc. for a Construction Permit, Docket # 2020-P-A-0018**

Dear Ms. Vest:

This letter shall serve to supplement the earlier submission by the undersigned dated July 16, 2020 regarding the application of Croda, Inc. ("Croda") for a construction permit. Specifically, in addition to previously-communicated concerns relating to Croda's permit application, we believe that the proposed additional emissions that would result if the permit were granted should be addressed with specificity.

The Route 9 Corridor has known cancer clusters that have existed for a long time. The Department of Natural Resources and Environmental Control ("DNREC") has been aware of this for years. As discussed below, there is reason to believe that the health issues in this area are directly related to the heavy industry that is in close proximity to the surrounding residential communities.

Furthermore, the number of COVID-19 cases in the Route 9 Corridor has been markedly higher than other areas in our State. At one point, the Corridor was a potential hot spot for the State of Delaware. The underlying health conditions of residents, as a result of industrial pollution, made these residents the most vulnerable and susceptible to the current pandemic. As such, additional emissions in the Corridor have the potential of being catastrophic and deadly.

Among other compelling reasons, DNREC should not allow additional emissions at this time due to the potentially devastating impact of the pandemic. Instead, DNREC, in conjunction with State health officials, at a minimum should compel heavy industry to reduce emissions during the pandemic.

As you are aware, the undersigned previously shared their concerns that Croda's operations posed a very serious threat to the well-being of the surrounding communities, and that Croda is ill-prepared to respond to any emergency at its plant. This fact was borne out with the release of ethylene oxide and the inadequate response thereto by Croda in November, 2018. In spite of this release and Croda's woefully insufficient response, Croda now provides assurances that this was a thing of the past and it has remedied its shortcomings with a functioning emergency warning system. This is not the case. Croda's emergency warning system was tested on August 11, 2020. It failed.

The concerns we have regarding the health threat to our constituents posed by Croda's proposed increase in emissions, especially ethylene oxide, does not come out of thin air. Indeed, the health concerns we have are supported by none other than the U.S. Environmental Protection Agency ("EPA"). Moreover, the EPA's 2014 National Air Toxics Assessment (released August 22, 2018), based on the updated cancer risk value for ethylene oxide, identified ethylene oxide as a significant driver of cancer risk in the New Castle area. As DNREC is well aware, this is the very same area in which Croda operates and proposes to increase its production and emissions of ethylene oxide.

As further evidence of the health threat (especially to New Castle, Delaware) posed by an expansion of ethylene oxide production at Croda's site, which would result if DNREC were to approve the permit application, we attach two documents that are incorporated by reference and we are submitting into the record: (1) *Communities at Risk from Air Toxics – Deeper Analysis of NATA Results and Tool for a Path Forward A&WMA's 112th Annual Conference & Exhibition Québec City, Québec June 25–28, 2019*; and (2) *Report: Management Alert - Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities About Health Concerns and Actions to Address Those Concerns*, Report #20-N-0128, March 31, 2020.

Finally, the EPA's Office of Inspector General recommended in March, 2020 that the EPA promptly provide residents in all communities near the 25 high-priority ethylene oxide-emitting facilities, which includes New Castle, Delaware, with a forum for an interactive exchange of information with EPA *or state personnel* regarding health concerns related to exposure to ethylene oxide. The EPA apparently has chosen as yet not to follow this recommendation. Nonetheless, pursuant to the OIG's recommendation, we are hereby requesting that DNREC promptly schedule a public forum to provide for such exchange of information with the public.

Very Truly Yours,

/s/ Jea Street

Councilman Jea Street

/s/ David Carter

Councilman David Carter

/s/ Penrose Hollins

President Pro Tempore  
Penrose Hollins

/s/ George Smiley

Councilman George Smiley

/s/ Karen Hartley-Nagle

Council President Karen  
Hartley-Nagle

/s/ Dee Durham

Councilwoman Dee Durham

/s/ Michael P. Migliore, Esq.

Michael P. Migliore



U.S. ENVIRONMENTAL PROTECTION AGENCY

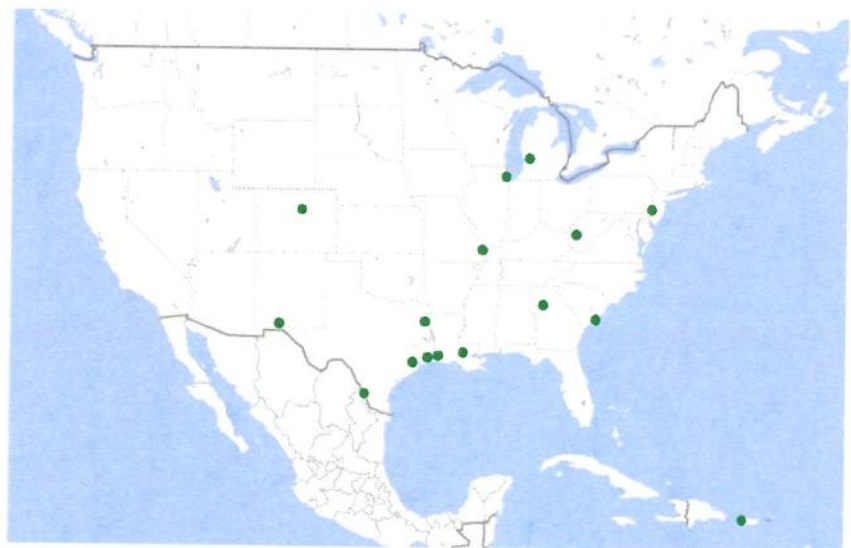
## OFFICE OF INSPECTOR GENERAL

*Improving air quality*

### **Management Alert:** Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities About Health Concerns and Actions to Address Those Concerns

Report No. 20-N-0128

March 31, 2020



**Report Contributors:**

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**Abbreviations**

EPA	U.S. Environmental Protection Agency
NATA	National Air Toxics Assessment
OIG	Office of Inspector General

**Cover Image:** Metropolitan areas in the United States where there is at least one census tract in which ethylene oxide is a significant risk driver for cancer. (OIG-developed image based on the 2014 NATA and information from the EPA)

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# At a Glance

## Why We Did This Project

While conducting an audit of the U.S. Environmental Protection Agency's actions to address air toxics emissions through its residual risk and technology review program, the EPA's Office of Inspector General identified an urgent matter related to whether the EPA had informed the public about health risks from exposure to ethylene oxide emissions. Therefore, we are issuing this management alert so that the EPA can address this matter while our overall audit work continues.

Ethylene oxide is a gas used to make other chemicals that are needed to manufacture a variety of products and to sterilize medical equipment. Studies show that breathing in elevated ethylene oxide levels over many years can lead to lymphoid cancers in males and females and breast cancer in females. In December 2016, the EPA revised its characterization of the chemical to "carcinogenic to humans."

This report addresses the following:

- Improving air quality.

Address inquiries to our public affairs office at (202) 566-2391 or [OIG WEBCOMMENTS@epa.gov](mailto:OIG_WEBCOMMENTS@epa.gov).

List of [OIG reports](#).

## **Management Alert:** Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities About Health Concerns and Actions to Address Those Concerns

### What We Found

Through its National Air Toxics Assessment, the EPA identified areas where exposure to ethylene oxide emissions could contribute to an elevated estimated lifetime cancer risk equal to or greater than 100 in one million, a risk level that the EPA generally considers not sufficiently protective of health. These emissions primarily come from chemical manufacturing plants and commercial sterilizers that sterilize medical equipment.

**The EPA needs to inform residents who live near facilities with significant ethylene oxide emissions about their elevated estimated cancer risks so they can manage their health risks.**

The EPA has prioritized activities to more fully assess ethylene oxide emissions and the associated health risks to the public near 25 high-priority facilities. These activities include communicating with facilities and states about gathering emissions information and communicating with elected officials about the National Air Toxics Assessment results. While the EPA or state personnel, or both, have met with residents living near nine of the 25 high-priority facilities, communities near 16 facilities have yet to be afforded public meetings or other direct outreach to learn about the health risks and actions being taken to address those risks.

The OIG did not identify any specific statutory, regulatory, or policy requirements for the EPA to provide the public additional information regarding its preliminary determination that certain ethylene oxide-emitting facilities may present health risks to surrounding communities. However, the EPA's mission statement includes working to ensure that "[a]ll parts of society ... have access to accurate information sufficient to effectively participate in managing human health and environmental risks." Thus, the Agency should work to ensure that the health risks and actions that the EPA is taking to address those risks are directly and promptly communicated to residents living near all the high-priority facilities.

### Recommendations and Planned Agency Corrective Actions

We recommend that the Agency provide residents in all communities near the 25 high-priority ethylene oxide-emitting facilities with a forum for an interactive exchange of information with EPA or state personnel regarding health concerns related to exposure to ethylene oxide. In its response to our draft report, the Agency proposed an alternative recommendation with corrective actions that focused on completing more refined investigations of risk prior to conducting significant public outreach. We do not believe that the Agency should delay providing forums for interactive outreach with residents in these communities. Therefore, our recommendation is unresolved pending receipt of an acceptable corrective action plan with milestones from the EPA.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

March 31, 2020

**MEMORANDUM**

**SUBJECT:** Management Alert: Prompt Action Needed to Inform Residents  
Living Near Ethylene Oxide-Emitting Facilities About Health Concerns  
and Actions to Address Those Concerns  
Report No. 20-N-0128

**FROM:** Sean W. O'Donnell

**TO:** Doug Benevento, Associate Deputy Administrator

While conducting an audit of the U.S. Environmental Protection Agency's actions to address air toxics emissions through its residual risk and technology review program ([Project No. OA&E-FY19-0091](#)), the EPA's Office of Inspector General identified an urgent matter to report to the Agency. The OIG is alerting you to this matter because of the disparity in the extent and nature of communication between the EPA and impacted communities where the EPA has identified significant health risks to the public from ethylene oxide emissions. This report presents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The EPA's Office of Air Quality Planning and Standards, within the Office of Air and Radiation, and EPA Regions 2-8 are responsible for the issues discussed in this report. Due to the significance of the issues and the involvement of multiple offices, the report is addressed to the associate deputy administrator.

**Action Required**

This report contains an unresolved recommendation. In accordance with EPA Manual 2750, the resolution process begins immediately with the issuance of this report. We are requesting a meeting within 30 days between the associate deputy administrator and the OIG's assistant inspector general for Audit and Evaluation. If resolution is still not reached, the Office of the Administrator is required to complete and submit a dispute resolution request to the chief financial officer.

We will post this report to our website at [www.epa.gov/oig](http://www.epa.gov/oig).



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# Chapter 1

## Introduction

### Purpose

While conducting the audit of the U.S. Environmental Protection Agency's actions to address air toxics emissions through its residual risk and technology review program (Project No. [OA&E-FY19-0091](#)), the EPA's Office of Inspector General identified an urgent matter to report to the Agency. This matter involves the communication of the EPA's current assessment of health risks to the public from exposure to ethylene oxide air emissions.

### Background

Ethylene oxide is a flammable and colorless gas used to make chemicals that are needed in the manufacturing of a variety of products including antifreeze, textiles, plastics, detergents, and adhesives. It is also used to sterilize medical equipment or other devices that cannot be sterilized by methods such as steam. A variety of sources emit ethylene oxide, including chemical manufacturing facilities and medical equipment sterilization facilities. Ethylene oxide is one of 187 hazardous air pollutants regulated by the EPA. Also known as air toxics, hazardous air pollutants are known or suspected to cause cancer or other serious health effects.

The EPA increased the cancer risk value for ethylene oxide in December 2016 based on studies from the National Institute for Occupational Safety and Health. The EPA found the chemical to be 30 times more carcinogenic to adults than previously thought, and the Agency revised ethylene oxide's carcinogenic description from "probably carcinogenic to humans" to "carcinogenic to humans." Studies show that breathing air containing elevated ethylene oxide levels over many years increases the risk of developing lymphoid cancers in males and females and breast cancer in females. For a single year of exposure to ethylene oxide, the risk of developing cancer is greater for children than for adults. This is because ethylene oxide can damage deoxyribonucleic acid, or DNA, which is hereditary material in humans.

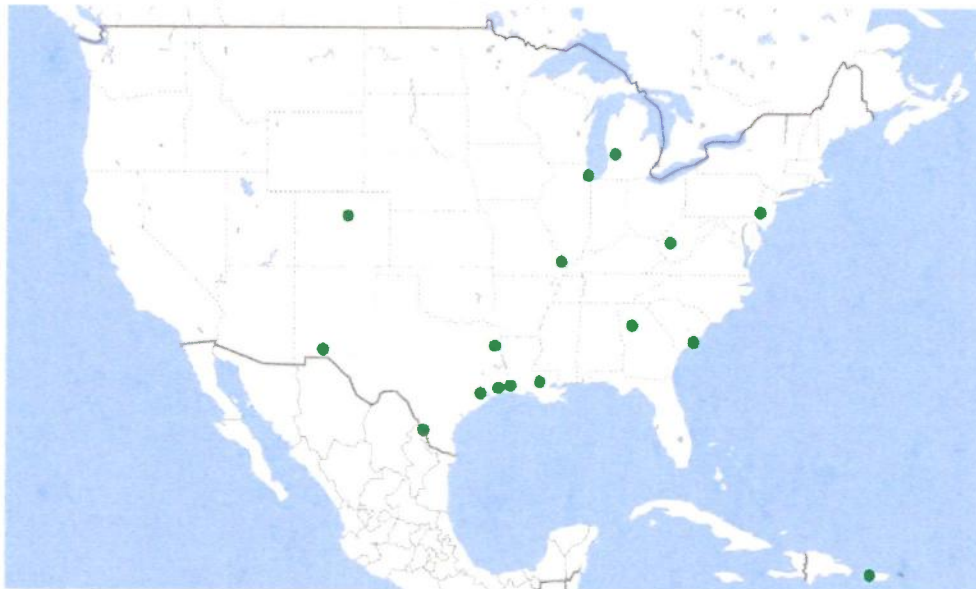
#### ***EPA Identified Ethylene Oxide as Significant Health Risk***

The EPA periodically conducts the National Air Toxics Assessment to assess the public health risk from exposure to air toxics. The EPA and state, local, and tribal air agencies use NATA as a screening tool to help them identify geographic areas, pollutants, or emission sources for further examination. Based on the updated cancer risk value for ethylene oxide, the EPA's 2014 NATA identified ethylene oxide as a new and significant driver of cancer risk. The 2014 NATA was released in 2018 but is based on emission inventories reported for calendar



year 2014. The EPA identified census tracts with elevated estimated cancer risks primarily driven by ethylene oxide emissions in 17 metropolitan areas, as shown in Figure 1. Census tracts are small, relatively permanent statistical subdivisions of a county with boundaries that normally follow visible features, such as roads and streams. Census tracts ideally contain about 4,000 people and 1,600 housing units.

**Figure 1: Metropolitan areas in the United States where there is at least one census tract in which ethylene oxide is the risk driver**



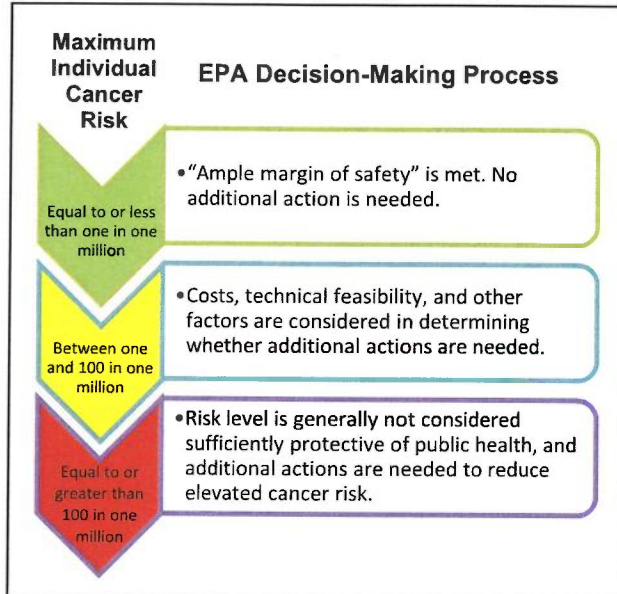
Source: 2014 NATA and information from the EPA.

Note: Two of the metropolitan areas—Allentown-Bethlehem-Easton in Pennsylvania and Philadelphia-Camden-Wilmington in Pennsylvania, New Jersey, and Delaware—overlap, so only 16 areas are identifiable on the map.

NATA presents cancer risk estimates based on a cumulative 70-year lifetime exposure. For example, a cancer risk of one in one million implies that if one million people are exposed to the same concentration of a pollutant continuously over 70 years, one person would likely develop cancer from the exposure. This risk would be in addition to any baseline cancer risk of a person not exposed to these air toxics. According to the EPA's March 1999 *Residual Risk Report to Congress*, for establishing air toxics emissions standards, the EPA generally considers a risk of 100 in one million (or one in 10,000) as not sufficiently protective of public health and requires additional action to reduce that risk. Figure 2 illustrates the EPA decision-making process when addressing residual risk from air toxics emissions. Residual risk is the health and environmental risk that remains after implementation of technology-based control standards that have already been promulgated to address air toxics emissions. The Clean Air Act Amendments of 1990 required the EPA to establish technology-based standards for sources of air toxics and, within eight years thereafter, review

the remaining health risk to the public and establish additional standards to reduce the public's health risk to acceptable levels, if necessary.

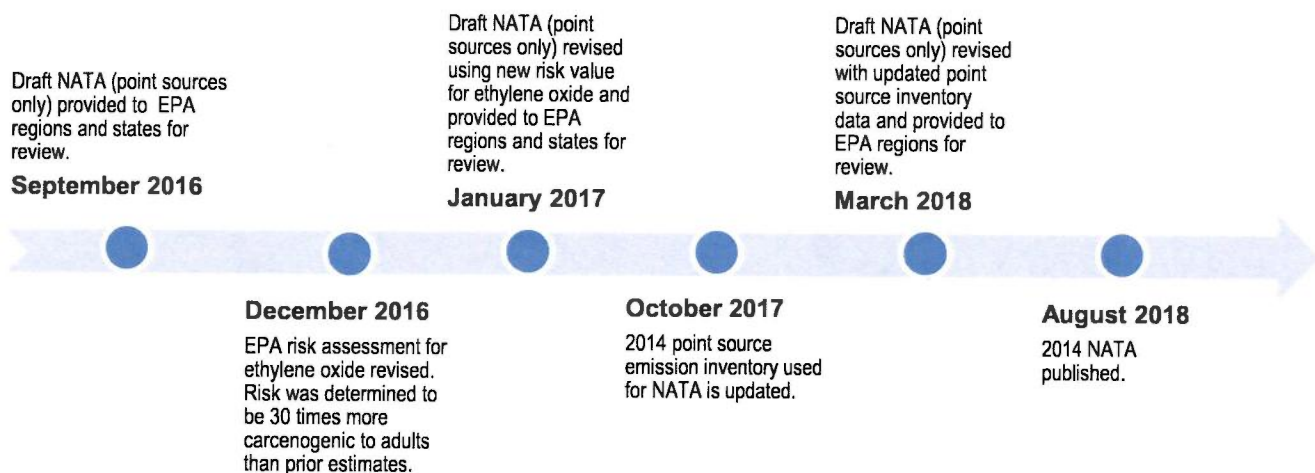
**Figure 2: EPA decision-making process for addressing residual risk in the Agency's regulatory program**



Source: OIG-developed based on information from the EPA.

The EPA released the 2014 NATA on August 22, 2018. Figure 3 provides a timeline of the development of the 2014 NATA.

**Figure 3: Timeline for developing the 2014 NATA data**



Source: OIG-developed based on information provided by the EPA.

Note: The first complete version of the 2014 NATA was provided to regions and states to review in June 2017, with a deadline of August 2017.

On August 29, 2018, the mayor of Willowbrook, Illinois, one community impacted by ethylene oxide emissions, held a public meeting to provide information and answer the community's questions regarding ethylene oxide. The meeting included the EPA, the Illinois Environmental Protection Agency, and the Agency for Toxic Substances and Disease Registry. Since that meeting, residents in other communities, as well as members of Congress, have expressed concerns about the public health risk from exposure to ethylene oxide emissions and what actions the EPA is taking to address those concerns.

### ***EPA's Approach for Addressing Risks from Ethylene Oxide***

As the EPA was finalizing the 2014 NATA, the Agency identified 22 ethylene oxide-emitting facilities that contribute to elevated estimated cancer risks equal to or greater than 100 in one million at the census tract level. According to the EPA, the Agency has prioritized taking actions to assess and address the health risks from these 22 facilities as well as three additional facilities that were estimated to contribute to elevated estimated cancer risks equal to or greater than 1,000 in one million at the census block level. Census blocks represent smaller statistical areas bounded by visible features, such as roads and streams, and by nonvisible boundaries, such as property lines. A block is the smallest geographic unit for which the U.S. Census Bureau tabulates decennial census data.

Eleven of these 25 facilities are commercial sterilizers, **which are** facilities that sterilize medical equipment, and 14 are chemical plants. Throughout this report, we refer to these 25 facilities, **which the EPA had previously designated as contributing to a high estimated cancer risk**, as "high-priority" facilities. Each of the 17 metropolitan areas identified previously in Figure 1 contains at least one of the 25 high-priority facilities.

Since the release of the 2014 NATA, the EPA has developed a two-pronged approach to address ethylene oxide emissions that consists of (1) reviewing existing regulations and (2) gathering information to inform regulatory efforts and determine whether more immediate reduction steps are necessary in any particular location.

**Regulatory review.** The first prong of the EPA's approach is to review existing air emissions regulations pertaining to facilities that emit ethylene oxide. On December 17, 2019, the EPA proposed revised emissions standards for miscellaneous organic chemical manufacturing facilities, some of which emit ethylene oxide. A court order requires that the EPA issue the final rule by May 29, 2020.<sup>1</sup> On December 12, 2019, the EPA published an advance notice of proposed rulemaking in the Federal Register to solicit information from industry

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<sup>1</sup> Pursuant to a court order issued on February 19, 2020, the deadline for the EPA to finalize revisions, if any, to the National Emission Standards for Hazardous Air Pollutants for the Miscellaneous Organic Chemical Manufacturing source category was modified from March 13, 2020, to May 29, 2020. See *California Communities Against Toxics, et al. v. Wheeler*, No. 1:15-cv-00512-TSC, order dated February 19, 2020.



and the public regarding a potential future rulemaking to revise the current standards for commercial ethylene oxide sterilization facilities. The existing standards for these two source categories were developed prior to the EPA revising the unit risk estimate for ethylene oxide, which increased the EPA's estimate of cancer risk to adults. Thus, a facility could be complying with the existing standards, but exposure to the facility's emissions could create elevated and unacceptable public health risks.

In addition to the two source categories discussed above, ethylene oxide is emitted by facilities in other source categories, such as synthetic organic chemical manufacturing and polyether polyols production. Ethylene oxide is also emitted at area sources, which are smaller facilities. Of the 25 high-priority facilities:

- Four are in the synthetic organic chemical manufacturing industry source category.
- Two are in the polyether polyols production source category.
- Seven are chemical plants categorized as area sources.

At the time we issued this report, the EPA had not yet scheduled regulatory reviews for these two source categories or the chemical plant area sources that emit ethylene oxide.

**Information gathering.** The second prong of the EPA's approach is to gather additional information about the facilities that emit ethylene oxide. This effort is intended to help inform the EPA's regulatory approach. It includes the EPA's efforts to work with states to identify opportunities for voluntary emission reductions in the near-term. The EPA is initially focusing its information gathering and voluntary reduction efforts on the 25 high-priority facilities.

## **Responsible Offices**

The EPA's Office of Air Quality Planning and Standards, within the Office of Air and Radiation, and EPA Regions 2–8 are responsible for the issues discussed in this report. Due to the significance of these issues and the involvement of multiple offices, this report has been addressed to the associate deputy administrator, who manages the regions.

## **Scope and Methodology**

We conducted our work related to this report from February 2019 to January 2020. While our overall audit, which is still ongoing, is being conducted in accordance with generally accepted government auditing standards, the work related to this report does not constitute an audit done in accordance with these standards.

We reviewed the EPA's mission statement; its guidance on risk communication; the EPA communications strategy, as well as regional communications plans to address ethylene oxide emissions; the 2014 NATA; the EPA-generated lists of ethylene oxide-emitting facilities that contribute to an estimated increased lifetime cancer risk of at least 100 in one million based on the 2014 NATA; and lists of additional facilities based on preliminary information of the elevated estimated cancer risks at the census block level.

We contacted EPA regions that had at least one facility contributing to elevated health risks to determine what actions they have taken to communicate with the public regarding the EPA's assessment of the public health risk from ethylene oxide emissions. We also interviewed staff and managers from the EPA's Office of Air Quality Planning and Standards to identify the EPA's approach to addressing risk from ethylene oxide facilities.

## **Chapter 2**

### **EPA Should Inform Residents Living Near All High-Priority Ethylene Oxide-Emitting Facilities of Health Concerns**

The EPA, state personnel, or both have met with residents living near nine of the 25 high-priority facilities where the EPA has estimated that ethylene oxide emissions significantly contribute to elevated estimated cancer risks. These meetings were held to inform the public and answer questions that residents had regarding ethylene oxide emission in their communities. In addition to public meetings, the EPA provided information on its website regarding activities to address ethylene oxide, and the seven EPA regions in which the high-priority facilities were located noted that they have informed states, elected officials, community advocates, or other interested parties about the ethylene oxide facilities contributing to elevated estimated cancer risks in their states.

Public meetings have not been conducted in communities near 16 facilities where the EPA estimated that ethylene oxide emissions contribute to elevated estimated cancer risks. These communities have not been given the same opportunity to interact with federal and state regulators to become informed on the issue. Some regions have taken action to correct this disparity. Region 2 plans to meet with residents living near one high-priority facility to inform them of health concerns. Additionally, Region 3 has a communications plan in place to work with state and local agencies on how they plan to inform communities near ethylene oxide-emitting facilities in that region, which includes four high-priority facilities. Similar plans to meet with communities near 11 high-priority facilities are not in place, most of which are in Texas and Louisiana in Region 6.

Appendix A lists the 25 high-priority facilities and whether EPA or state personnel have directly informed residents living near those facilities about their health risks.

### **Communities Should Have Access to Information to Help Manage Health Risks**

The OIG did not identify any statutory, regulatory, or policy requirements for the EPA to provide the public additional information regarding its preliminary determination that certain ethylene oxide-emitting facilities may present health risks to surrounding communities. The EPA's mission statement, however, states that the Agency works to ensure that "[a]ll parts of society—communities, individuals, businesses, and state, local and tribal governments—have access to accurate information sufficient to effectively participate in managing human health and environmental risks."



In addition, in our July 2019 report titled *FY 2019: EPA Management Challenges*, Report No. 19-N-0235, we noted that one of the EPA's management challenges is to improve risk communication by providing individuals and communities with sufficient information to make informed decisions to protect their health and the environment. EPA Administrator Andrew Wheeler identified risk communication as one of his top priorities in his July 2018 speech to EPA employees, stating:

Risk communication goes to the heart of EPA's mission of protecting public health and the environment. We must be able to speak with one voice and clearly explain to the American people the relevant environmental and health risks that they face, that their families face and that their children face.

Further, the EPA's risk communication guidance states that a "cardinal rule" of risk communication is to accept and involve the public as a legitimate partner.<sup>2</sup> The guidance also states that communities have the right to participate in decision-making processes that affect their lives and livelihoods.

To fulfill its mission statement and risk communication principles, the EPA should assure that all impacted communities are provided an opportunity to engage in an interactive exchange of information with the EPA and state agencies to more fully understand the health concerns related to ethylene oxide exposure and the actions that the EPA is taking to address those concerns.

## **EPA or State Agencies Have Held Public Meetings with Residents Living Near Nine High-Priority Facilities**

The EPA, state agencies, or both have met with the residents near nine high-priority facilities located in four EPA regions to discuss health concerns related to ethylene oxide emissions:

- **Region 4.** The first two public meetings in Region 4 were held on August 19 and August 20, 2019, regarding cancer risks from ethylene oxide emissions from commercial sterilization facilities in Smyrna and Covington, Georgia. These meetings were held after residents learned about their cancer risks in July 2019 through the news media, almost a year after the 2014 NATA was released.

On December 2, 2019, Region 4 attended a public meeting in Charleston, South Carolina, with residents living near another high-priority facility. At this meeting, the chief of the Bureau of Air Quality from the South

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<sup>2</sup> EPA, *Risk Communication in Action—the Risk Communication Workbook*, EPA/625/R-05/003, August 2007; and EPA, *Risk Communication in Action—the Tools of Message Mapping*, EPA/625/R-06/012, August 2007.

Carolina Department of Health and Environmental Control gave a presentation about NATA and ethylene oxide.

- **Region 5.** The first public meeting regarding ethylene oxide concerns was held on August 29, 2018, in Willowbrook, Illinois, a community near a commercial sterilization facility. As previously mentioned, this meeting was arranged by the mayor one week after the EPA released the 2014 NATA. The EPA and other agencies provided information and answered the community's questions. More than 400 people attended, according to a meeting summary. The EPA hosted a second public meeting, which consisted of an open house and a public forum, on November 29, 2018. The EPA also held a third public meeting on May 29, 2019, to discuss the EPA's risk assessment summary of the ethylene oxide emissions from the Willowbrook facility.

State agency personnel held public meetings with residents living near ethylene oxide-emitting facilities in Grand Rapids, Michigan, and Lake County, Illinois.

- **Region 7.** Regional personnel held public meetings with residents living near two high-priority facilities in Verona, Missouri, and Jackson, Missouri. The last meeting was held on December 2, 2019.
- **Region 8.** Regional and state agency personnel met with residents near one high-priority facility in Lakewood, Colorado, on December 11, 2018.

Public meetings have been used to inform residents of ethylene oxide concerns at the nine high-priority facilities discussed above. However, EPA and state personnel could use other risk communication tools—such as webinars, workshops, and door-to-door communication—to discuss health concerns and take questions from the residents living near the remaining 16 high-priority facilities.

## **EPA Plans to Conduct Direct Outreach Efforts to Inform Residents Living Near Five High-Priority Facilities**

The EPA has plans to conduct public outreach to residents near five high-priority facilities located in two EPA regions to discuss health concerns related to ethylene oxide emissions:

- **Region 2.** Regional personnel plans to meet with residents living near a high-priority facility in Puerto Rico in spring 2020.
- **Region 3.** The Region, which has four high-priority facilities that emit ethylene oxide, has developed a strategic risk communication plan to work with state and local agencies on how they will inform communities that may be in areas of concern. This plan consists of various proposed

activities during the first half of 2020, such as meetings with city councils and door-to-door communication.

## **EPA Does Not Have Plans to Conduct Direct Outreach Efforts to Inform Residents Living Near 11 High-Priority Facilities**

The EPA does not have plans to hold public meetings or otherwise directly inform residents living near 11 high-priority facilities of health risks. One of these facilities is in Region 5 and ten are in Region 6.

Region 6 provided us with a draft communication plan, which stated that it will collaborate with states on community meetings and further public outreach. The plan did not, however, include time frames for conducting public meetings or any other direct outreach by the EPA. Furthermore, Region 6 personnel told us that Texas and Louisiana state agency personnel would take the lead in informing the public about health risks from ethylene oxide emissions. Region 6 personnel stated that as of January 2020, regional, Louisiana, and Texas state agency personnel had not communicated with the communities near the high-priority facilities.

## **Conclusions**

The EPA and state agencies have conducted a variety of outreach efforts to communicate health concerns associated with ethylene oxide emissions. The EPA or state agencies have held public meetings in communities near nine ethylene oxide emitting facilities to inform the public about ethylene oxide emissions in their communities. However, public meetings or other direct outreach efforts have not been afforded to residents living near 16 of the high-priority ethylene oxide-emitting facilities. Although Regions 2 and 3 have plans to work with states and one territory to communicate with residents living near the high-priority facilities in those respective regions, there are still communities around 11 high-priority facilities where the EPA has no plans for direct outreach with residents about health risks from ethylene oxide emissions.

While we recognize that state agency personnel can play a lead role in these meetings, the EPA's participation is important for two reasons:

- To provide a consistent message.
- To fulfill the EPA's critical leadership role in developing any future regulatory standards for ethylene oxide-emitting facilities under the Agency's two-pronged approach to address ethylene oxide emissions.



## Recommendation

We recommend that the associate deputy administrator:

1. Improve and continue to implement ongoing risk communication efforts by promptly providing residents in all communities near the 25 ethylene oxide-emitting facilities identified as high-priority by the EPA with a forum for an interactive exchange of information with the EPA or the states regarding health concerns related to exposure to ethylene oxide.

## Agency Response and OIG Assessment

The EPA offered an alternative recommendation to the OIG's draft report recommendation. The alternative recommendation stated:

Improve, as necessary, and continue to implement ongoing efforts to conduct additional, more refined investigation of risks in all high-risk areas. Based on this work, support state/territory-led efforts to communicate risk information to residents in all communities near ethylene oxide-emitting facilities in high priority areas.

The Agency's response also offered three corrective actions to implement its proposed recommendation, but these proposed actions did not provide a timeline for when the more refined investigation of risks would be completed and when the residents would be informed of the results. The Agency's response to our draft report is included in Appendix B.

In the absence of an acceptable corrective action plan, we continue to recommend that the Agency promptly provide residents with a forum for an interactive exchange of information on the risks of ethylene oxide to their communities. We agree that the Agency should continue its ongoing efforts to conduct additional, more refined investigations of risks for communities near the 25 high-priority facilities and the census block facilities. However, these efforts should not preclude the Agency and the respective states from promptly informing the communities near the high-priority facilities about the NATA results and the actions that the EPA and the states are taking to address public health concerns associated with ethylene oxide emissions. This will help assure that all residents near high-priority facilities have access to similar information and the opportunity to manage their personal health risk.

Our recommendation is considered unresolved. We are requesting a meeting within 30 days between the associate deputy administrator and the OIG's assistant inspector general for Audit and Evaluation.

## ***Status of Recommendations and Potential Monetary Benefits***

### RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status <sup>1</sup>	Action Official	Planned Completion Date	Potential Monetary Benefits (in \$000s)
1	11	Improve and continue to implement ongoing risk communication efforts by promptly providing residents in all communities near the 25 ethylene oxide-emitting facilities identified as high-priority by the EPA with a forum for an interactive exchange of information with the EPA or the states regarding health concerns related to exposure to ethylene oxide.	U	Associate Deputy Administrator		

<sup>1</sup> C = Corrective action completed.

R = Recommendation resolved with corrective action pending.

U = Recommendation unresolved with resolution efforts in progress.

***EPA or State Actions to Directly Inform  
Residents Living Near 25 High-Priority  
Ethylene Oxide-Emitting Facilities of Health Risks***

EPA region	Facility	Location	Type of facility	Date of first EPA or state action to directly inform residents living near facility
2	Edwards Lifesciences Corp.	Anasco, PR	Commercial sterilizer	Planned for spring 2020.
3	B Braun Medical Inc.	Allentown, PA	Commercial sterilizer	Communications plan identifies potential outreach activities for first half of calendar year 2020.
3	Union Carbide Corp. – Institute	Institute, WV	Chemical plant	Communications plan identifies potential outreach activities for first half of calendar year 2020.
3	Croda	New Castle, DE	Chemical plant	Communications plan identifies potential outreach activities for first half of calendar year 2020.
3	Union Carbide Corp. – South Charleston Facility	South Charleston, WV	Chemical plant	Communications plan identifies potential outreach activities for first half of calendar year 2020.
4	Solvay USA (Lanxess)	Charleston, SC	Chemical plant	December 2, 2019
4	C R Bard (Becton, Dickinson, and Co.)	Covington, GA	Commercial sterilizer	August 20, 2019
4	Griffith Micro Science Inc. (Sterigenics)	Smyrna, GA	Commercial sterilizer	August 19, 2019
5	Sterigenics US	Willowbrook, IL	Commercial sterilizer	August 29, 2018
5	Medline Industries, Northpoint Services Division	Waukegan, IL	Commercial sterilizer	May 23, 2019
5	Medtronic Sterile Systems Operation (Viant Medical)	Grand Rapids, MI	Commercial sterilizer	March 6, 2019
5	Air Products Performance Manufacturing (Evonik)	Milton, WI	Chemical plant	None
6	BCP Ingredients	St. Gabriel, LA	Chemical plant	None
6	Union Carbide Corp., St Charles Operations	Taft, LA	Chemical plant	None
6	Huntsman, Port Neches Operations	Port Neches, TX	Chemical plant	None
6	Eastman Chemical Texas Operations	Longview, TX	Chemical plant	None
6	Taminco US (Eastman Corp.)	St. Gabriel, LA	Chemical plant	None
6	Sasol Chemicals (USA) – Lake Charles Chemical Complex	Westlake, LA	Chemical plant	None



EPA region	Facility	Location	Type of facility	Date of first EPA or state action to directly inform residents living near facility
6	Air Products Performance Manufacturing Inc. – Reserve Plant (Evonik Materials Corp.)	Reserve, LA	Chemical plant	None
6	Midwest Sterilization Corp.	Laredo, TX	Commercial sterilizer	None
6	Shell Technology Center Houston	Houston, TX	Chemical plant	None
6	Sterigenics Santa Teresa Facility	Santa Teresa, NM	Commercial sterilizer	None
7	Midwest Sterilization Corp.	Jackson, MO	Commercial sterilizer	December 2, 2019
7	BCP Ingredients – Verona Plant	Verona, MO	Chemical plant	October 11, 2019
8	Terumo BCT Sterilization Services	Lakewood, CO	Commercial sterilizer	December 11, 2018

Source: The OIG developed the table using data from EPA-generated lists of facilities contributing to elevated estimated cancer risks at the census tract level in the 2014 NATA and the census block level and information from regions.

Note: The EPA prioritized 25 facilities: 22 that contribute to elevated estimated cancer risk equal to or greater than 100 in one million at the census tract level and three that contribute to elevated estimated cancer risks equal to or greater than 1,000 in one million at the census block level. The three facilities prioritized at the census block level are Union Carbide–South Charleston Facility in Region 3, Air Products Performance Manufacturing (Evonik) in Wisconsin in Region 5, and BCP Ingredients Verona Plant in Region 7.

## Agency Comments on Draft Report



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

January 31, 2020

#### **MEMORANDUM**

**SUBJECT:** Response to Office of Inspector General Management Alert

"Prompt Action Needed to Communicate Risks to Residents Living Near Facilities with Significant Ethylene Oxide Emissions," Project No. OA&E-FY19-0091 (January 24, 2020)

**FROM:** Douglas Benevento, Associate Deputy Administrator (/s/ January 31, 2020)

**TO:** James L. Hatfield, Director, Air Directorate  
Office of Audit and Evaluation  
Office of Inspector General

Thank you for the opportunity to respond to the issues and recommendation identified in the subject draft report from EPA's Office of Inspector General (OIG). Following is a summary of EPA's overall response to the draft report, along with its position on the recommendation. For those aspects of the report with which the Agency does not agree, we have explained our position.

Ethylene oxide is one of the 187 hazardous air pollutants that EPA regulates under the Clean Air Act (CAA), and it has been determined to be carcinogenic to humans. It also is a chemical that is important both to society and public health, as a building block for making other chemicals and in its use for sterilizing medical devices that cannot be sterilized using other methods. According to the Food and Drug Administration (FDA), nearly 20 billion medical devices are sterilized with ethylene oxide every year.<sup>3</sup>

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<sup>3</sup> *Statement on concerns with medical device ability due to certain sterilization facility closures, October 25, 2019, available at <https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures>*

EPA continues to make progress on a suite of actions to address ethylene oxide emissions while working closely with other federal partners and appreciates the opportunity to respond to the draft report on this important topic. As EPA pursues its mission to protect public health and the environment, we take our work very seriously and provide these responses for your consideration.

Consistent with the Agency's two-pronged approach for addressing air emissions of ethylene oxide, EPA will continue to work with affected state and local air agencies to look more closely at emissions from facilities and to emphasize the need for public outreach with respect to census tracts where the Agency's National Air Toxics Assessment (NATA) identified potentially elevated risk from ethylene oxide. We also wish to emphasize the complex, interrelated environmental and public health concerns around the use of ethylene oxide and hope your office understands both these concerns and that there is much more to learn about this chemical.

#### Executive Summary

In general, we find that much of the draft report is factually correct but wish to provide several line edits in the interest of improving its accuracy (see Attachment A). We do wish to highlight two important issues that have not received sufficient attention in the draft report: (1) the importance of conducting additional, more refined investigation of risks based on NATA results prior to conducting significant direct outreach with the public; and (2) recognition of the role that other government agencies should play in public outreach. Finally, we acknowledge the disparity in the extent and nature of communication between EPA and affected communities, and we offer several corrective actions for your consideration.

#### Background: Status of EPA's Efforts to Address Ethylene Oxide

In this section, we review EPA's statutory authority to regulate ethylene oxide, two existing CAA regulations covering ethylene oxide, and the status of our efforts to review those regulations. In addition, we provide an update on area-specific outreach activities.

The 2014 NATA, released in August 2018, identified potentially elevated health risks from ethylene oxide exposure in the air in a number of census tracts across the country. Since NATA's release, EPA has been taking a two-pronged approach to address emissions. In the first prong, the Agency is reviewing its CAA regulations for industrial facilities that emit ethylene oxide. An update on the status of our work on two CAA National Emission Standards for Hazardous Air Pollutants (NESHAP) addressing ethylene oxide is provided below. In the second prong, we have been working closely with state and local air agencies as they work to get additional information on facility emissions to determine whether more immediate emission reduction steps are necessary or possible in higher risk areas. This work is ongoing, and there have already been significant emission reductions in several areas. Also, as part of the second prong, we have been working with local and state environmental and public health professionals, as well as ensuring that elected leadership in affected communities are informed. The draft report summarizes some, but not all, of the work being done to communicate with the public.

*Statutory Authority:* EPA has existing CAA rules for industries that emit ethylene oxide. On July 16, 1992 (57 FR 31576), EPA published a list of sources for which NESHAP were to be

promulgated (referred to as the “source category list”). Under Section 112 of the CAA, EPA first promulgates technology-based standards for categories of sources identified as emitting one or more of the hazardous air pollutants listed in CAA section 112(b), which include ethylene oxide. Then, the law requires that EPA evaluate those technology-based standards to determine whether additional standards are needed to address any remaining risk associated with emissions of hazardous air pollutants. This second step is commonly referred to as the “residual risk review.” When combined with the CAA-required periodic review of the technologies used by facilities in the source categories, this review is commonly referred to as a “risk and technology review.” As described further below, rules for facilities in two of these listed source categories are currently being reviewed.

Once EPA sets or revises a national standard, facilities must get (or update) CAA Operating Permits from the state where the source is located or, in a few cases, from EPA. These permits list requirements to control air pollution that apply to the source. Facilities must comply with these permits or face penalties.

*Rulemaking Actions:* To ensure that its rules are defensible and sustainable, the Agency needs to build a solid, data-based record for its decisions. For the reviews of the NESHAP for Miscellaneous Organic Chemical Manufacturing (MON) facilities and the NESHAP for Ethylene Oxide Commercial Sterilizers, EPA is responsible for compiling information on emissions, potential control technology options, and costs for the many potentially affected facilities in these source categories.

For the MON source category, the existing technology-based rule was promulgated in November 2001 (68 FR 63852). There were several amendments after that date. EPA is under a court order to issue a final CAA-required risk and technology review of the MON rule by March 13, 2020. On November 1, 2019, the Agency signed a proposed rulemaking for the MON. This proposed rule was published in the Federal Register on December 17, 2019<sup>4</sup>, and EPA held two public hearings in January 2020. The public comment period on this proposed rule closes on February 18, 2020. In this action, EPA is proposing significant emission reductions of ethylene oxide from covered facilities in order to reduce risks. EPA evaluated the risks posed by air toxics, including ethylene oxide, from this source category and proposed that cancer risks for this source category are unacceptable. To reduce risks to an acceptable level, EPA is proposing additional requirements for process vents, storage tanks, and equipment in ethylene oxide service.

For the Ethylene Oxide Commercial Sterilizers source category, the existing technology-based NESHAP was first promulgated in December 1994 (59 FR 62585). There were several amendments regarding control requirements after that date. A residual risk and technology review was completed in April 2006 (67 FR 17712).

EPA is in the process of soliciting and collecting information about commercial sterilizers, and we expect to take rulemaking action in mid-2020. Over the past year, EPA’s Office of Air and Radiation has been gathering data to support its review of the Ethylene Oxide Commercial

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<sup>4</sup> See <https://www.federalregister.gov/documents/2019/12/17/2019-24573/national-emission-standards-for-hazardous-air-pollutants-miscellaneous-organic-chemical>



Sterilizers NESHAP. One challenge that we have identified for this source category is that about one-third of the more than 100 potentially affected facilities are small businesses. Given the potential impact of certain emission reduction strategies on these small businesses, the Agency has requested nominations for representatives of potentially affected small entities to advise a Small Business Advocacy Review (SBAR) Panel before the Agency takes any significant regulatory action. Further, to obtain additional data needed to support a formal notice-and-comment rulemaking, the Agency has recently taken two actions under the CAA. First, on December 5, 2019, EPA signed an Advance Notice of Proposed Rulemaking (published in the Federal Register on December 12, 2019<sup>5</sup>), which provides an avenue for interested parties to give us additional data and information about commercial sterilizers to inform a proposed rulemaking. Second, also in December 2019, EPA issued a request for information under CAA section 114 to several commercial sterilization companies, which requires these companies to provide information about their operations and control systems for each ethylene oxide sterilization facility that they own. In the months ahead, we plan to issue a proposed rule informed by the data collected via the ANPRM and section 114 requests, and, if necessary, by the SBAR Panel process. The proposal will solicit public comment on potential regulatory approaches and emission controls, and EPA will provide the opportunity for a public hearing. Once EPA has considered public input, EPA would then issue a final rule.

*Area-Specific Activities:* Because our rulemaking process takes time, we decided that more immediate action is necessary in higher risk areas identified by NATA. Our Regional offices have been working with affected state and local air agencies to look more closely at emissions from facilities in these areas. The purposes of this work are: to provide information to refine risk estimates; to help us as we review our regulations; and to identify whether it is possible to achieve early emission reductions, thereby reducing potential health risks to the public. Please note that in some Regions this work has included not only facilities in the higher risk areas identified by NATA, but also other facilities that emit ethylene oxide. Also, some Regions did not have higher-risk areas identified by NATA based on census tract-level screening criteria.

#### Response to Results Highlighted in the Report

*Importance of conducting additional, more refined investigation of risks based on NATA results:* NATA tells us where to look closer at potential risks in certain communities – it does *not* provide final, definitive risk information. EPA notes this on the NATA website: “EPA developed NATA as a screening tool for state, local and tribal air agencies. NATA’s results help these agencies identify which pollutants, emission sources and places they may wish to study further to better understand any possible risks to public health from air toxics.”<sup>6</sup>

Because NATA is a screen, additional work often is necessary to more fully understand the risks that NATA identifies as being potentially elevated. This step should be conducted prior to significant public outreach to community residents for two key reasons:

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<sup>5</sup> See <https://www.federalregister.gov/documents/2019/12/12/2019-26804/national-emission-standards-for-hazardous-air-pollutants-ethylene-oxide-commercial-sterilization-and>

<sup>6</sup> See <https://www.epa.gov/national-air-toxics-assessment/nata-overview>

1. NATA relies on existing emissions inventory information, which is several years old by the time the assessment is released. Specifically, EPA uses facility and emissions information from the 40,000 facilities included in the National Emissions Inventory (NEI), combined with census blocks as defined by the U.S. Census Bureau, to model ambient concentrations of pollutants at the block level. To develop risk estimates by census tract, these block-level concentrations are aggregated by taking a population-weighted average that results in a tract-level concentration. This concentration is then adjusted for exposure (e.g., commuting patterns) and used to develop risk estimates by census tract.<sup>7, 8</sup> The NATA released in August 2018 relied on the 2014 NEI, which was the most recent available. While attempts to verify emissions information are made during NATA's development, additional verification is necessary to determine whether the emissions estimates in the NEI are correct.
2. NATA presents results at the census tract level, which is the smallest geographic area at which it is appropriate to present NATA screening-level estimates of risk given inputs such as mobile source emissions, which are input to the model via gridded emissions rather than a single point. However, even census tract-level information may be somewhat uncertain.<sup>9</sup>

EPA cautions NATA users that more investigation may be necessary, noting on the NATA website that “(w)e suggest you use NATA results cautiously. The uncertainty – and thus the accuracy – of the results varies by place and by pollutant. Often, more localized studies are needed to better characterize local-level risk. These studies often include air monitoring and more detailed modeling.” The website also describes several important NATA limitations that need to be considered when looking at the results, including use of default assumptions and pollutant concentrations based on computer model simulations, not real-world measurements. EPA also reminds NATA users to keep in mind that the assessment's results:

- apply best to larger areas, not specific places;
- apply to groups, not to specific people;
- assume a person breathes the air toxics emitted in the analysis every day for 70 years;
- reflect just some of the variation in background pollutant concentrations;
- may give concentrations that are too high or too low for some air toxics and in some places;
- make some assumptions when data are missing or in error;
- may not accurately capture sources that emit only at certain times; and

<sup>7</sup> Technical Support Document for the 2014 National Air Toxics Assessment, 6.4.1. Model Results for Point Sources: Aggregation to Tract-level Results, p. 135, available at [https://www.epa.gov/sites/production/files/2018-09/documents/2014\\_nata\\_technical\\_support\\_document.pdf](https://www.epa.gov/sites/production/files/2018-09/documents/2014_nata_technical_support_document.pdf)

<sup>8</sup> While the screening-level NATA does not provide block level information, EPA does generate and consider block-level risk information for major sources of air toxics emissions in its regulatory program. Specifically, EPA generally conducts risk assessments at the block level when setting and reviewing a NESHAP. In these risk assessments, block-level risk information, including risk results, undergoes intensive quality assurance reviews.

<sup>9</sup> See, for example, EPA's Technical Support Document for the 2014 NATA, which notes that “(a)lthough results are reported at the census tract level, average risk estimates are far more uncertain at this level of spatial resolution than at the county or state level.” Technical Support Document for the 2014 National Air Toxics Assessment, 7.2.2. Quantifying Variability, p. 141, available at [https://www.epa.gov/sites/production/files/2018-09/documents/2014\\_nata\\_technical\\_support\\_document.pdf](https://www.epa.gov/sites/production/files/2018-09/documents/2014_nata_technical_support_document.pdf)

- include risk estimates that are uncertain.<sup>10</sup>

EPA recommends that the draft management alert be revised to reflect the need for additional, more refined investigation of risks prior to holding public meetings or conducting significant public outreach in communities where NATA identifies potentially elevated risk. The OIG's report should recognize the critical importance of providing information that is as detailed and up-to-date as possible when communicating risk.

*Role of other government agencies in public outreach:* The draft report fails to recognize the important role that other federal government agencies play in addressing ethylene oxide. The Food and Drug Administration is involved given the importance of ethylene oxide in sterilizing medical devices. Because half of the medical devices in the U.S. that require sterilization are sterilized with ethylene oxide<sup>11</sup>, FDA is monitoring supplies in light of the permanent closure of one sterilizer in Willowbrook, Illinois, and the temporary closure of others. In addition, in the fall of 2019, FDA issued two public innovation challenges to encourage the development of new approaches for sterilizing medical devices.

The Agency for Toxic Substances and Disease Registry (ATSDR) is involved given the potential public health issues related to ethylene oxide emissions. In Illinois, ATSDR has conducted a risk assessment for people living in the areas of the commercial sterilizer in Willowbrook, Illinois, and also is working on a health consultation related to ethylene oxide emissions from two facilities in Lake County, Illinois.

A consistent, coordinated government-wide response is appropriate when communicating with the public about ethylene oxide. EPA recommends that the draft report be revised to reflect the role that other federal government agencies play in addressing ethylene oxide.

*Response to the report's recommendation:* The draft report recommends that the Associate Deputy Administrator improve and continue to implement ongoing risk communication efforts by promptly providing residents in all communities near the 25 ethylene oxide-emitting facilities that EPA identified as high-priority with a forum for and interactive exchange of information with the EPA and/or states regarding health concerns related to exposure to ethylene oxide. We offer edits to the recommendation in Attachment A. In response to the recommendation, we offer three corrective actions:

1. EPA will continue to implement ongoing efforts to conduct additional, more refined investigation of risks based on NATA screening-level results in all high-risk areas and will improve those efforts as necessary. Based on this work, EPA will also continue to support state/territory-led efforts to communicate risk information to residents in communities near industrial sources of interest.

<sup>10</sup> NATA Limitations, available at: <https://www.epa.gov/national-air-toxics-assessment/nata-limitations>

<sup>11</sup> *Reduction of Ethylene Oxide Sterilization Emissions for Medical Devices and Potential for Utilizing Other Sterilization Modalities*, FDA, page 3. Available at <https://www.fda.gov/media/132186/download>

2. The Wisconsin Department of Natural Resources (WDNR) is coordinating efforts to respond to potential ethylene oxide risks to the community near Evonik Industries in Milton, Wisconsin. EPA Region 5 is supporting WDNR efforts. This facility is regulated under Wisconsin's state air toxics rule (NR445), and the state has worked with the company for many years to reduce emissions. On June 24-25, 2019, WDNR and Region 5 conducted a joint inspection of the facility, which included leak detection and repair monitoring, and the state found no evidence of noncompliance. Since then, Region 5 has provided technical assistance to WDNR to help verify Evonik's emissions. The state has raised significant questions regarding the NATA screening-level results and is refining the analysis for the facility. Once we have a more complete assessment risk from the facility, EPA will support, as requested, state-led efforts to communicate risk information to residents in the community.
3. For the 10 high-priority industrial facilities in Region 6, EPA will continue its dialogue with the states of Louisiana and Texas to offer technical support and assistance to conduct additional, more refined investigation of risks based on updated NATA screening-level results. In addition, EPA will support, as requested, state-led efforts to communicate risk information to residents in communities near these facilities.

In closing, as we noted in the opening of this letter, EPA will continue to work with affected state and local air agencies to look more closely at emissions from facilities and to emphasize the need for public outreach with respect to census tracts where NATA identified potentially elevated risk from ethylene oxide. We will continue to provide both technical and outreach support where needed – e.g., reviewing monitoring plans or assisting with the development or review of outreach materials, as requested. In addition, the Agency is continuing to move ahead with planned public meetings where states or territories have requested our assistance. Finally, please note that EPA's Office of Air and Radiation will provide training on the importance of community engagement, best practices on planning for community engagement, and options for conducting meetings.

If you have any questions concerning our response, please contact Michael Koerber, Deputy Director, Office of Air Quality Planning & Standards, (919) 541-5557.

Attachment

In consideration of the Agency's technical comments to the draft management alert, the OIG made several revisions to the final report to incorporate additional information where appropriate. These technical comments have not been included in this Appendix.



## ***Distribution***

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# Communities at Risk from Air Toxics – Deeper Analysis of NATA Results and Tool for a Path Forward

**A&WMA's 112th Annual Conference & Exhibition**

Québec City, Québec

June 25–28, 2019

**Abstract #600376**

**Phil Norwood, Steve Fudge, Jill Mozier**

**SC&A Incorporated**

**Chapel Hill, North Carolina**

## ABSTRACT

The US Environmental Protection Agency's (EPA's) National Air Toxics Assessment (NATA) is a state-of-the-science tool to inform both national and localized efforts to collect air toxics information, characterize emissions and help prioritize pollutants and areas of interest for further study to gain a better understanding of risks. In the most recent version of NATA, released on August 22, 2018, the EPA estimated that several communities are exposed to cancer risks greater than 100-in-1 million, which is the level generally considered as the upper limit of acceptable risk. Some of these communities are exposed to cancer risks approaching 1,000-in-1 million, or an order of magnitude greater than the upper limit of acceptability.

In this analysis, we take a deeper look at populations in these communities to estimate the number of people that are predicted to be exposed to elevated cancer risks due to the inhalation of or air toxics. We also evaluate the number of individuals in various demographic groups that are exposed to these higher risks.

The EPA clearly points out that the NATA is a screening tool. Communities may wish to perform more rigorous risk assessments to obtain more accurate estimates of the risks in the communities and to more accurately pinpoint the causes of these risks. In this paper, we also provide steps for such a refined assessment by highlighting the EPA's Human Exposure Model (HEM), which is a ready-made tool that can help state or local agencies, community groups, industry, or the general public perform these more refined assessments.

## INTRODUCTION

The National Air Toxics Assessment (NATA) is the US Environmental Protection Agency's (EPA's) ongoing review of air toxics in the United States. EPA developed NATA as a screening tool for state, local and tribal air agencies and the results can help these agencies identify which pollutants, emission sources and locations they may wish to study further, to better understand any possible risks to public health from air toxics. NATA provides a "snapshot" of chronic risks due to the long-term exposure to emissions of air toxics over several years. The sources of air toxic emissions studied in NATA include large and small stationary sources, stationary and non-stationary area sources, and mobile sources.

Specifically, NATA predicts cancer risks, which are defined as “the probability of contracting cancer over the course of a lifetime”, assuming continuous exposure. It also calculates the hazard quotients, which are ratios of the potential exposure to the toxic air pollutant and the level at which no adverse effects are expected. A hazard quotient less than or equal to one indicates that adverse noncancer effects are not likely to occur, and thus can be considered to have negligible hazard. NATA also reports hazard indices (HI), which represent the sum of hazard quotients for toxics that affect the same target organ or organ system. A hazard index of 1 or lower means air toxics are unlikely to cause adverse noncancer health effects over a lifetime of exposure, to that organ or organ system. For our analysis, we focused on cancer risks.

The 1989 Benzene National Emission Standards for Hazardous Air Pollutants (NESHAP) rule set up a two-step, risk-based decision framework for the NESHAP program. This rule and framework are described in more detail in EPA's 1999 Residual Risk Report to Congress.<sup>1</sup> First, the rule sets an upper limit of acceptable risk at about a 1-in-10,000 (or 100-in-1 million) lifetime cancer risk for the most exposed person. As the rule explains, “The EPA will generally presume that if the risk to that individual [the Maximum Individual Risk] is no higher than approximately 1 in 10 thousand, that risk level is considered acceptable and EPA then considers the other health and risk factors to complete an overall judgment on acceptability.”

Second, the benzene rule set a target of protecting the most people possible to an individual lifetime risk level no higher than about 1-in-1 million. These determinations called for considering other health and risk factors, including risk assessment uncertainty, in making an overall judgment on risk acceptability.

The evaluation presented in this paper is focused on communities estimated at high cancer risks in the 2014 NATA. Specifically, it examines communities for which NATA predicted cancer risks of 100-in-1 million or greater. In this paper, we use the terminology “unacceptable cancer risk” to refer to a predicted cancer risk of 100-in-1 million or greater. We also use the terminology “high-risk community” to characterize communities where the average predicted cancer risk is 100-in-1 million or greater. Finally, we examine the number of people in these communities that are exposed to these potential health risks. This includes an appraisal of the demographic and socioeconomic makeup of these communities where higher cancer risks are predicted.

## PROJECT APPROACH AND RESULTS

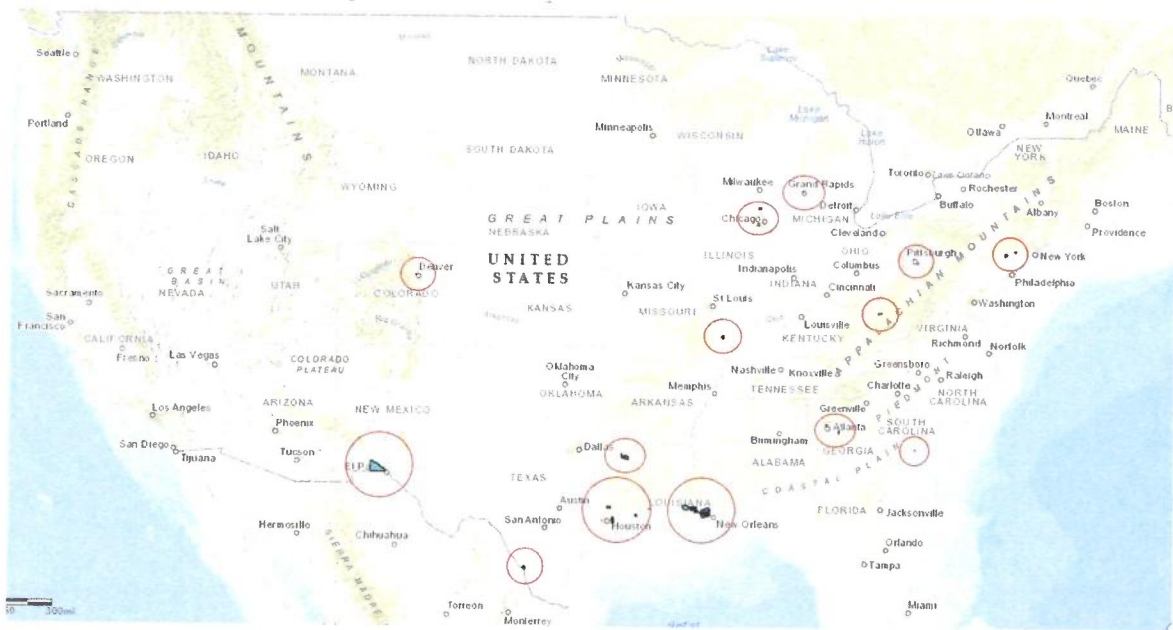
Our objective was to evaluate the estimated cancer risks for communities with NATA-reported “high” cancer risks. As discussed above, EPA has established a cancer-risk threshold of 100-in-1 million to represent an upper limit of acceptable risk. We selected this as the definition of “high-risk.” Next, we selected the definition of a “community.” NATA results are provided by census tract. The US Census Bureau defines tracts as “small, relatively permanent statistical subdivisions of a county”. Census tracts generally have a population size between 1,200 and 8,000 people, with an average size of 4,000 people.<sup>2</sup> Sometimes, census tracts are characterized as “neighborhoods”.<sup>3</sup> Therefore, for the purposes of this analysis, we consider a census tract to represent a community. Throughout this paper, we use the terms “tract” and “community” interchangeably.

The approach that we used consisted of three steps. First, we obtained the nationwide tract-level cancer risks from NATA (specifically the 2014 NATA natl cancer risk by source group (XLS) spreadsheet)<sup>4</sup> and



sorted the tracts by the total cancer risk. Cancer risks are typically reported by the EPA to one significant figure, so we selected all tracts with predicted cancer risks of 95 or greater. The results of the 2014 NATA show 117 tracts/communities with an average cancer risk of 100-in-1-million or greater. We will refer to these tracts throughout this paper as “high-risk communities”. Figure 1 illustrates the locations of the communities (not including Puerto Rico). These 117 communities are in 27 counties/parishes in 14 states/commonwealths. Louisiana is the state with the largest number of these high-risk communities (34), followed by Texas (28), Pennsylvania (21), and Illinois (12). The counties/parishes with the largest numbers of high-risk communities are Lehigh County, Pennsylvania (15); St. John the Baptist Parish, Louisiana (12); and Harris County, Texas (11). This information is provided in Table 1.

**Figure 1. Location of High-Risk Communities in the United States**

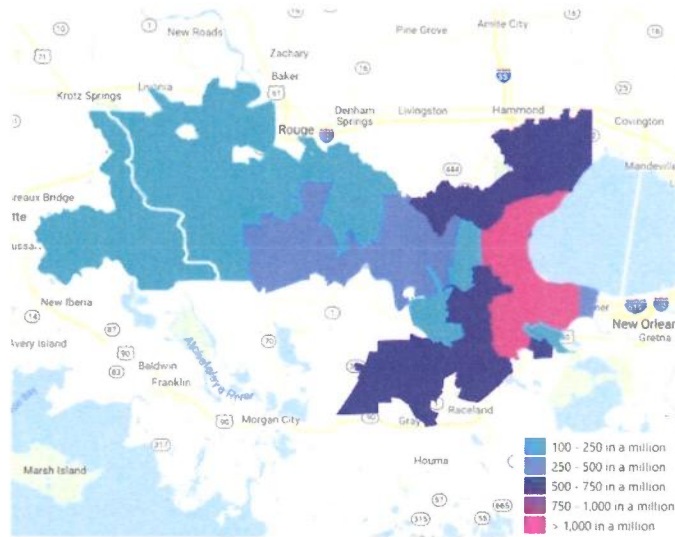


**Table 1. Location and Number of High-Risk Census Tracts/Communities from 2014 NATA**

<b>State/Commonwealth (Number of High-Risk Communities)</b>	<b>County/Parish</b>	<b>Number of Communities with Average Cancer Risk Estimated to be 100-in-1 million or greater in NATA</b>
Colorado (4)	Jefferson	4
Delaware (1)	New Castle	1
Georgia (4)	Fulton	3
	Newton	1
Illinois (12)	DuPage	8
	Lake	4
Louisiana (34)	Ascension	6
	Calcasieu	2
	Iberville	5
	St. Charles	7
	St. James	2
	St. John the Baptist	12
Michigan (1)	Kent	1
Missouri (1)	Cape Girardeau	1
New Jersey (1)	Warren	1
New Mexico (1)	Dona Ana	1
Pennsylvania (21)	Allegheny	3
	Lehigh	15
	Northampton	3
Puerto Rico (1)	Anasco	1
South Carolina (2)	Charleston	2
Texas (28)	Harris	11
	Harrison	2
	Jefferson	9
	Montgomery	1
	Webb	5
West Virginia (6)	Kanawha	6
<b>Totals</b>	<b>27</b>	<b>117</b>

The area of the country with the greatest concentration of high-risk communities is along the corridor between Baton Rouge and New Orleans. Figure 2 shows these communities. This figure also delineates the level of cancer risk predicted for each tract/community.

**Figure 2. High-Risk Communities in the Baton Rouge Area**



The next step in our analysis was to obtain information from the NATA results regarding the drivers of the cancer risks in these high-risk communities. NATA provides a breakdown of the cancer risk both by pollutant and by general source type that contributes to the risk. Of the 71 air toxics that were included in the NATA assessment, only 14 contributed 1% or more to the tract-level risks reported. These were: 1,3-Butadiene, Acetaldehyde, Acrylonitrile, Benzene, Benzyl Chloride, Chromium VI (Hexavalent), Carbon Tetrachloride, Chloroprene, Coke Oven Emissions, Ethylene Dichloride (1,2-Dichloroethane), Ethylene Oxide, Formaldehyde, Hydrazine, and Naphthalene. For most of the 117 high-risk communities examined, ethylene oxide is the most prevalent and significant contributor to tract-level risk. For 48 of the 117 high-risk communities (41%), over 75% of the predicted cancer risk was caused by ethylene oxide. Two other air toxics also contributed significantly to the high cancer risks – chloroprene and formaldehyde. The risk for the community with the highest predicted cancer risk, in St. John the Baptist parish in Louisiana, was driven by chloroprene. The combined cancer risks caused by these three air toxics (ethylene oxide, chloroprene, and formaldehyde) contributed more than 75% of the risk for 116 of the 117 high-risk communities. Table 2 summarizes the air toxics that contribute most significantly to the estimated cancer risks in these high-risk communities.

**Table 2. Contribution of Individual Air Toxics to the Predicted Cancer Risks**

Air Toxic	# of High-Risk Communities where the Air Toxic Contributes Specific Percentages to the Tract-Level Average Risk			
	>75%	>25%	>10%	>1%
1,3-Butadiene	0	0	0	54
Acetaldehyde	0	0	0	91
Acrylonitrile	0	0	0	7
Benzene	0	0	0	94
Benzyl Chloride	0	0	0	2
Carbon Tetrachloride	0	0	0	104
Chloroprene	1	7	20	22
Chromium VI (Hexavalent)	0	0	1	6
Coke Oven Emissions	0	3	3	3
Ethylene Dichloride (1,2-Dichloroethane)	0	0	0	13
Ethylene Oxide	48	113	114	114
Formaldehyde	0	8	78	117
Hydrazine	0	0	1	2
Naphthalene	0	0	0	69

NATA also provides information regarding the sources that contribute to the estimated tract-level cancer risks. Specifically, NATA reports the cancer risk from the following broad categories of emission sources:

- Stationary “point” sources,
- Non-point (area) sources,
- On-road mobile sources,
- Non-road mobile sources,
- Fire sources, and
- Biogenic sources.

Non-point, on-road, and non-road categories are further broken down into smaller general subcategories. For example, risks from non-road sources are reported for subcategories associated with recreational pleasure craft, construction, commercial lawn and garden, residential lawn and garden, agriculture, commercial equipment, ports, locomotives, airports, and railyards.

Background cancer risks and cancer risks from secondary formation of air toxics are also provided. Background risks are due to air toxic concentrations that exist in the air that do not come from a specific source. They may come from a natural source or from distance sources. Background concentrations can explain pollutant concentrations found even without recent human-caused emissions. Regarding secondary formation related risks, chemicals emitted from a source can be transformed into other chemicals in the air. In this case, the transformed chemical can be toxic and contribute to the cancer risk. In NATA, EPA predicted the secondary formation of the air toxics acetaldehyde, acrolein and formaldehyde in the atmosphere, along with the decay of 1,3-butadiene to acrolein.

Of the 38 categories and subcategories of sources reported in the NATA results, only 12 contributed more than 1% to the average tract-level cancer risk in these high-risk communities. These included the

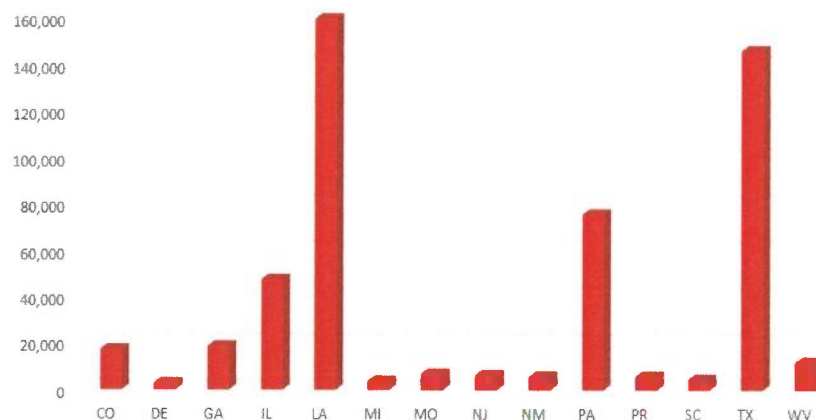


categories of stationary point sources, onroad sources, nonroad sources, nonpoint sources, fires, and biogenics. Air toxics formed from secondary formation and background also contributed to the high cancer risks. Table 3 provides a breakdown of the subcategories and the number of communities where they significantly contributed to the cancer risk. As can be seen in the table, stationary point sources clearly are the largest contributors to the cancer risks in these high-risk communities. Examples of stationary point sources include large industrial facilities, such as power plants, petroleum refineries, chemical manufacturing plants, pulp and paper mills, and numerous other industrial facilities.

**Table 2. Contribution of Sources to the Predicted Cancer Risks**

Air Toxic	# of High-Risk Communities where the Source Contributes Specific Percentages to the Tract-Level Average Risk			
	>75%	>25%	>10%	>1%
Stationary Point	71	117	117	117
Onroad LightDuty-OffNetwork-Gas	0	0	0	56
Onroad LightDuty-OnNetwork-Gas	0	0	0	19
Onroad HeavyDuty-Hoteling	0	0	0	1
Nonroad Airports	0	0	0	1
Nonpoint Oil Gas	0	0	0	1
Nonpoint Solvents Coatings	0	0	0	14
Nonpoint Residential Wood Combustion	0	0	0	20
Fire	0	0	0	44
Biogenics	0	0	0	86
Secondary Formation	0	1	62	117
Background	0	0	0	104

**Figure 3. Populations Living in High-Risk Communities by State**



The final step of our analyses involved investigating the populations exposed to these high risks. Figure 3 illustrates the number of people living in these high-risk communities by state/commonwealth. This information is summarized by county/parish in Table 3. There are over half a million people that live in the communities that are exposed to these “unacceptable” cancer risks due to the inhalation of air toxics. The number of people exposed to these high cancer risks correlates with the number of census

tracts/communities that showed cancer risks greater than 100-in-1-million, meaning that more people in Louisiana, Texas, and Pennsylvania are exposed.

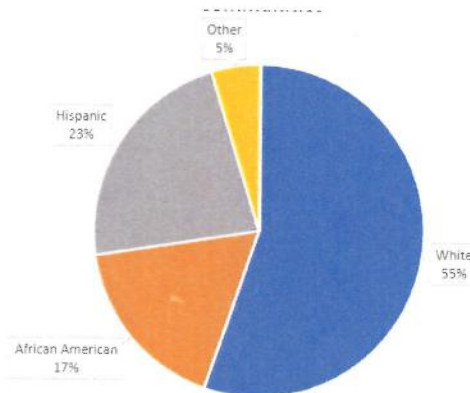
**Table 3. Population in High-Risk Communities**

State/Commonwealth	County/Parish	Population in Communities with Risks of 100-in-1- million or greater
Colorado	Jefferson	17,468
Delaware	New Castle	2,848
Georgia	Fulton	10,484
	Newton	8,377
	<b>State Total</b>	<b>18,861</b>
Illinois	DuPage	28,289
	Lake	19,370
	<b>State Total</b>	<b>47,659</b>
Louisiana	Ascension	55,776
	Calcasieu	7,311
	Iberville	22,537
	St. Charles	22,440
	St. James	7,432
	St. John the Baptist	45,924
	<b>State Total</b>	<b>161,420</b>
Michigan	Kent	3,869
Missouri	Cape Girardeau	6,908
New Jersey	Warren	6,461
New Mexico	Dona Ana	5,842
Pennsylvania	Allegheny	8,044
	Lehigh	60,126
	Northampton	7,692
	<b>Commonwealth Total</b>	<b>75,862</b>
Puerto Rico	Anasco	5,979
South Carolina	Charleston	4,680
Texas	Harris	59,818
	Harrison	8,356
	Jefferson	37,937
	Montgomery	10,144
	Webb	30,121
	<b>State Total</b>	<b>146,376</b>
West Virginia	Kanawha	12,067
<b>Grand Total</b>	—	<b>516,300</b>

We then explored these populations more closely, examining several broad demographic parameters of the populations that live in these 117 high-risk communities. We obtained the tract-level population demographic information from working files compiled in EPA's Environmental Justice Screening and Mapping Tool, EJSCREEN.<sup>5</sup> The data compiled in EJSCREEN are originally derived from the Census' American Community Survey (ACS) 5-year averages for 2010-2014.<sup>6</sup> Results from this demographic analysis include:

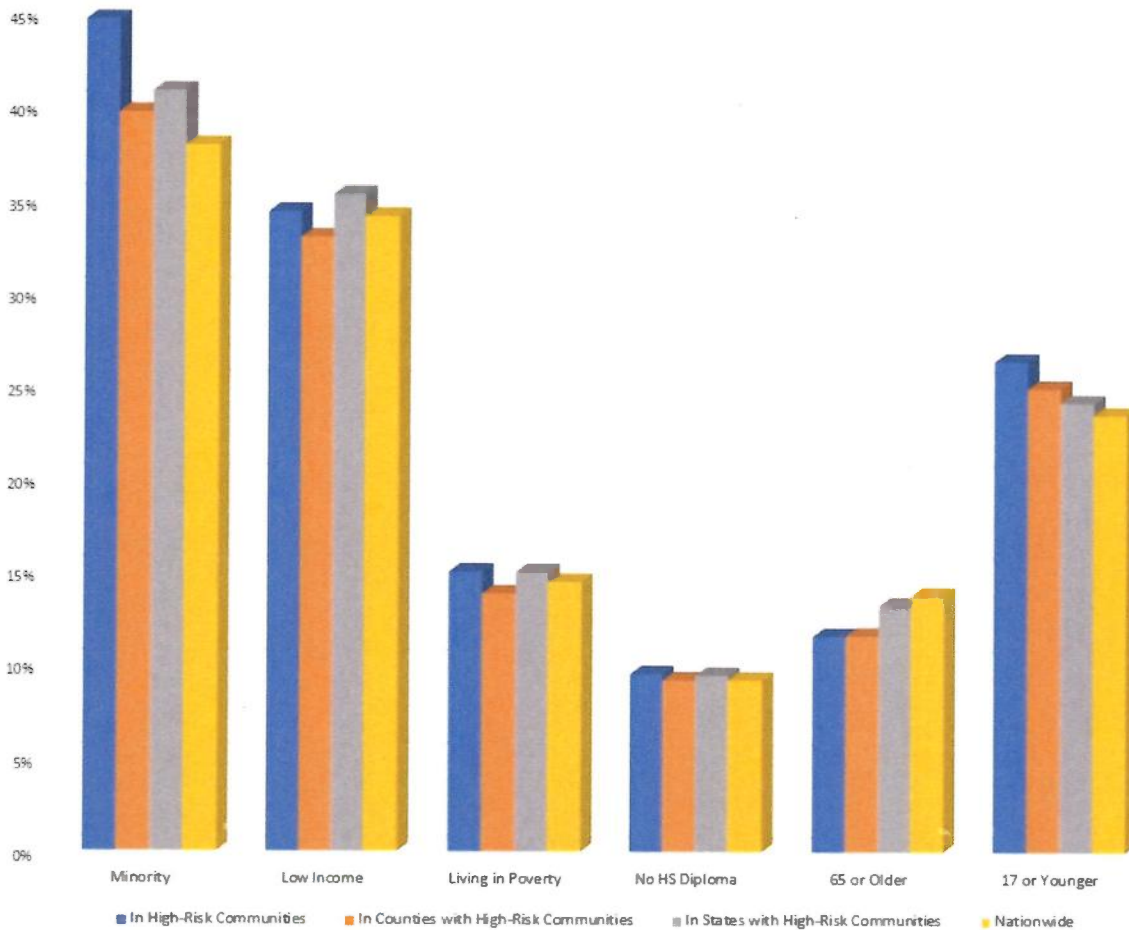
- Around 45% of the individuals living in these high-risk communities are minorities (Figure 4 provides a breakdown of these individuals by race);
- Almost 35% of the individuals living in these high-risk communities are considered "low income," and around 15% are living at or below the poverty level.
- Approximately 10% of the adult individuals living in these high-risk communities did not graduate from high school;
- Just under 12% of the individuals living in these high-risk communities are age 65 or older.
- Over 26% of the individuals living in these high-risk communities are age 17 or younger.

**Figure 4. Racial Makeup of Populations Living in High-Risk Communities**



In order to provide context for this demographic information, we compared these percentages to larger segments of the population in the United States. Specifically, we compared them to the percentages of the same parameters for (1) the counties in which the communities are located, (2) the states in which the communities are located, and (3) nationwide. Figure 5 illustrates these comparisons for the total population of all 117 communities.

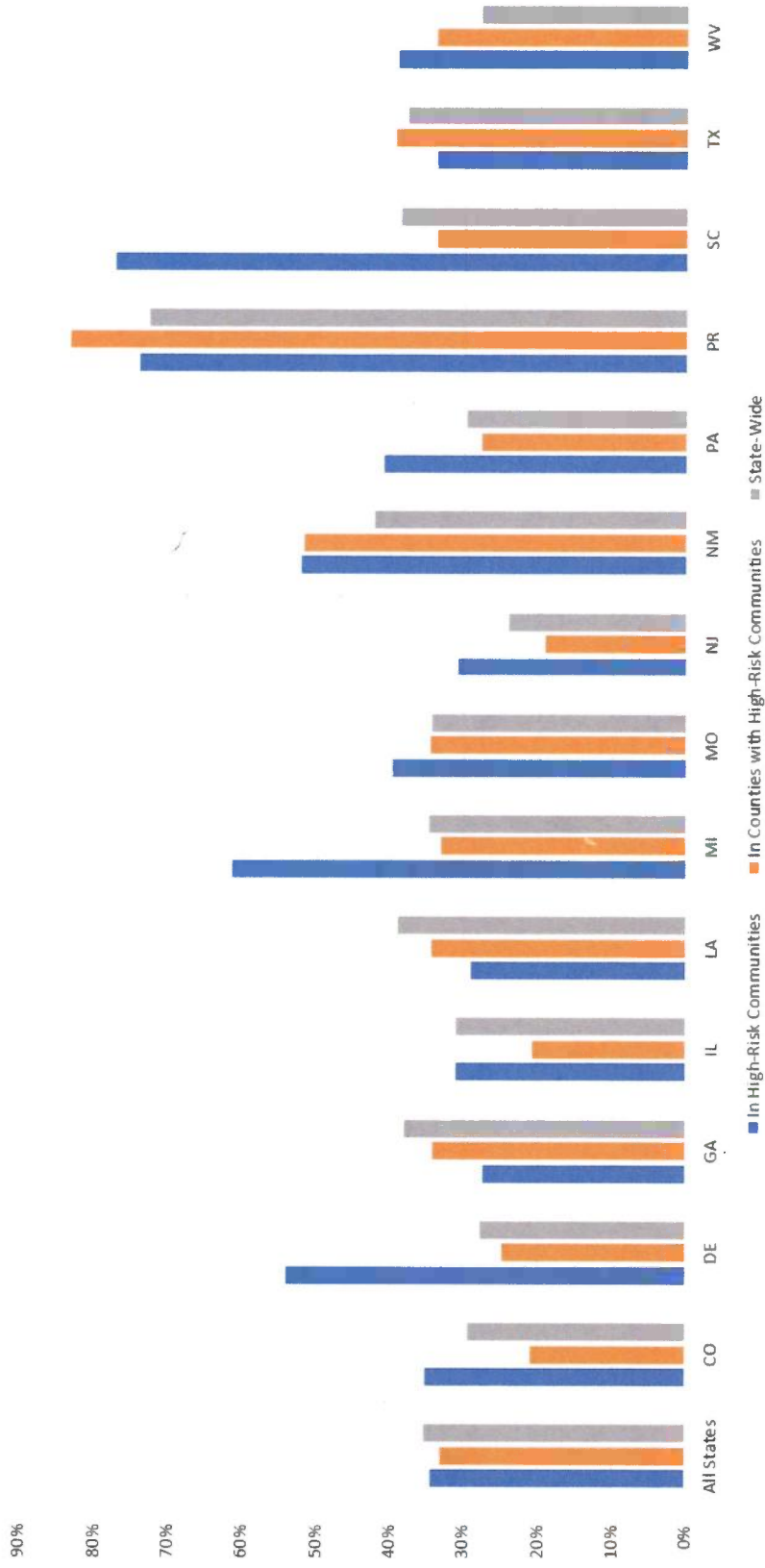
**Figure 5. Percentages of Populations in Specific Demographics**



Other than the slightly higher percentage of minorities in the high-risk communities and the slightly higher percentages of people 17 years old and younger, none of the other demographic parameters show a major difference between the high-risk communities and the other segments of the population. However, this is not the case when this information is broken down by state. Figure 6 provides a comparison of the high-risk community, county, and state for low-income populations. For 8 of the 14 states/commonwealths in which these high-risk communities are located, the percentage of the population in the high-risk communities that is low-income is higher than both the county-wide and state-wide percentages of these demographic populations. (For three states, the percentage of low-income population in the high-risk communities is lower than both the county and state levels.) This same basic trend is evident for the percentage of the population that are minorities, populations living below the poverty level, and for populations that do not have a high school degree. Figures analogous to Figure 6 for these parameters, as well as for populations 65 years old and greater, and populations 17 years old and younger, are provided in Appendix A.



Figure 6. Percentages of Low-Income Populations



## APPROACH FOR COMMUNITIES MOVING FORWARD

As a reminder, EPA clarifies that NATA is only a screening tool. As can be seen from the brief analyses presented in the earlier section, there is quite a bit of information that can be gleaned from NATA results and other publicly available data. However, there are questions that a state or local agency or a community would need to answer to be able to better assess the risks and the causes, and to begin to develop solutions to reduce the risks. Perhaps the two most key questions are:

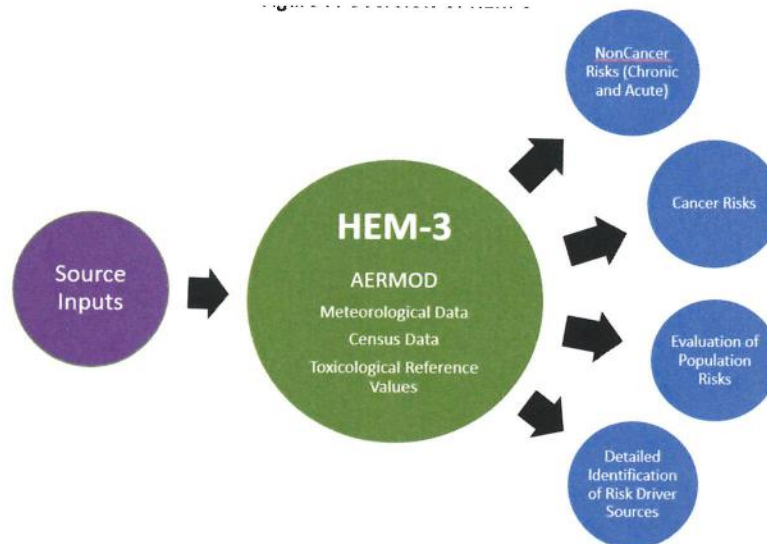
1. Where exactly are the individuals that are exposed to the highest risks? and
2. What are the specific sources that are causing the risk?

The resources needed to answer these questions can be overwhelming. One of the dangers that can occur is spending resources on improvements to the risk assessment that may not provide substantial value in obtaining the basic answers needed to move forward.

### Human Exposure Model (HEM-3)

We offer a progressive approach that does initial evaluations with readily available data and tools, followed by targeted refinements informed by the previous phases. The foundation of this resource-efficient approach is the Human Exposure Model, or HEM. HEM (HEM-3), version 1.5 is the most current version, and it is available on the EPA website.<sup>7</sup> There are two HEM-3 applications: (1) the single facility version and (2) the multi-facility version. The multi-facility version is the one best suited to conduct community-level risk assessments, as it can account for the complete range of sources of air toxics in an area and estimate the cumulative impacts and risks.

**Figure 7. Overview of HEM-3**



HEM-3 evaluates cancer risks, as well as chronic and acute non-cancer health effects, and population exposures due to emissions of air toxics. The HEM-3 model framework uses EPA's state-of-the-science AERMOD dispersion model on an unprecedented scale. It also contains 2010 Census data (at the census block level), as well as databases containing nationwide meteorological data and toxicological reference values. A simple view of HEM-3's inputs and outputs is provided in Figure 7.

HEM-3 allows the user to consider elevation and terrain, complex source configurations, temporal and wind variations, as well as building downwash effects. The user can also estimate ambient concentrations of pollutants considering additional dispersion factors such as wet and dry deposition and depletion, which allows estimation of multimedia concentrations and the effects of changes in those concentrations. While the 2014 NATA was conducted using AERMOD and large regional photochemical grid models, HEM-3 was used for previous versions of NATA to model stationary point sources, onroad sources, nonroad sources, nonpoint sources, fires, and biogenics across the entire nation.

There are many aspects of HEM-3 that can add efficiency to a community-based risk assessment. In the following we focus on six of these aspects.

1. **Meteorological Data.** AERMOD requires surface and upper air meteorological data that meet specific format requirements. Because HEM-3 has the meteorological data included, there is no need to obtain and process meteorological data. HEM-3 includes a library of meteorological data from National Weather Service (NWS) observation stations. The current HEM-3 AERMOD Meteorological Library includes over 800 nationwide locations. HEM-3 automatically obtains the meteorological data for the station nearest the source/community. However, the user has the option of selecting a different NWS station, or to provide and upload their own processed meteorological data into HEM-3 (e.g., from a community-based station).
2. **Receptor Locations.** HEM-3 automatically establishes receptors at the geographic centroid of each census block in the modeling domain. For each of these receptors, HEM-3 contains coordinates, the elevation, and the controlling hill height. Obtaining block-level results immediately provides considerable refinement to the tract-level results reported in NATA. HEM-3 also has location information for over 125,000 schools in the U.S., along with over 1,000 ambient air monitoring locations. Receptors can be added for these locations, as well as any other user-defined location.
3. **Impacts of Multiple Pollutants.** HEM-3 analyzes multiple pollutants concurrently, with the capability of including particulate and gaseous pollutants in the same model run.
4. **Contribution of Individual Sources.** HEM-3 calculates (and saves) the contribution from every source modeled to every toxic air pollutant concentration at every receptor. This allows the user to pinpoint the specific sources (e.g., a specific stack at an industrial facility) that cause elevated risks.
5. **Toxicological Reference Values.** For each air toxic that is classified as a hazardous air pollutant (HAP) in the Clean Air Act, the HEM-3 Chemical Health Effects Library includes the following parameters, where available: (1) unit risk estimate (URE) for cancer; (2) reference concentration (RfC) for chronic noncancer health effects; (3) reference benchmark concentration for acute health effects; and (4) target organs affected by the chemical (for chronic noncancer effects). These parameters are based on the EPA's database of recommended dose response values for HAP,<sup>8</sup> which is updated periodically, consistent with continued research on these parameters. HEM-3 also allows users to replace these reference values with user-defined values.
6. **Census Data.** As noted above, HEM-3 automatically establishes receptors at the geographic centroid of every census block in the modeling domain. In addition to the coordinates, elevation, and controlling hill height, HEM-3 also includes the population in each block. HEM-3 assumes that all individuals living in the census block are exposed to the concentration/risk predicted at the centroid. This allows the swift determinations of the number of individuals exposed to various risk levels. Note that while HEM-3 only contains total population of each census block, SC&A has developed for



the EPA an add-on to HEM-3 that provides assessment of the risks by various demographic and socioeconomic groups. Note that this “Environmental Justice Risk and Proximity Analysis Tool” is not currently available on EPA’s website.

### Simplified HEM-3 Based Approach to Assess Community Risks from Air Toxics

Your community has been identified in NATA as a high-risk community, or other information is available that raises a concern about the risk to residents resulting from the inhalation of air toxics. You need to obtain more information - but resources are limited. Figure 8 illustrates a HEM-3 based iterative approach that can both inform a community about the severity of the air toxics problem and start the process of corrective measures to improve it.

As illustrated in the first section of this paper, the NATA provides a great deal of screening-level information that can aid communities in determining the extent of the air toxics problem. However, there are limiting factors to the NATA results. Three of the most significant are (1) the results are average risks across relatively large geographic areas (i.e., census tracts), (2) there are no acute risks evaluated, and (3) the pollutant and source drivers are only provided at a high level.

The source input data used for NATA is EPA’s National Emissions Inventory (NEI).<sup>9</sup> HEM-3’s source input files are based on using NEI data, so it is a low hurdle to perform a preliminary assessment using the same NEI data used in NATA. This would provide considerably more detail regarding the two significant limitations noted above.

First, a HEM-3 assessment would provide census block results. Census blocks are the smallest geographic group for which the Census provides data and contain, on average, about 50 people. In a city, a census block often looks like a city block bounded on all sides by streets. Census blocks in suburban and rural areas may be large, irregular, and bounded by a variety of features, such as roads, streams, and transmission lines. In remote areas, census blocks may be geographically large. The number of census blocks in a tract can vary considerably.

Census Tract # 22095070800 in St. John the Baptist Parish, Louisiana, was the tract that showed the highest average cancer risk in the NATA results. Figure 9 shows this tract, along with the approximately 45 census blocks contained in it. As pollutants disperse from a source, a few hundred feet can make a significant difference in the concentration, and thus the risk. It is very easy to see how the average concentration across this 2-square mile tract would not represent the risk to individuals living very near the source.

To illustrate this further, we conducted a HEM-3 model run for a single facility in the Midwest using publicly-available NEI data. The average risk reported in NATA for the tract nearest this facility was 80-in-1 million. Our HEM-3 run resulted in block-level risks that ranged from 1 to 8,000-in 1 million. In other words, there are individuals living near this facility that are exposed to cancer risks 80 times greater than the level generally considered to be unacceptable. This sample tract has a population of 5,445 who are exposed to a NATA average risk of 80-in-1 million. The HEM-3 block-level results within this tract show 35 blocks with a risk of 100-in-1 million or greater affecting 656 people, and 14 blocks with a risk of 1,000-in-1 million or greater affecting 152 people. Figure 10 shows the risks across the census tract. The primary point of this example model run is to illustrate that individuals in many communities across the country are likely exposed to unacceptable cancer risks due to air toxics even if this is not indicated by the very broad tract-level NATA results.



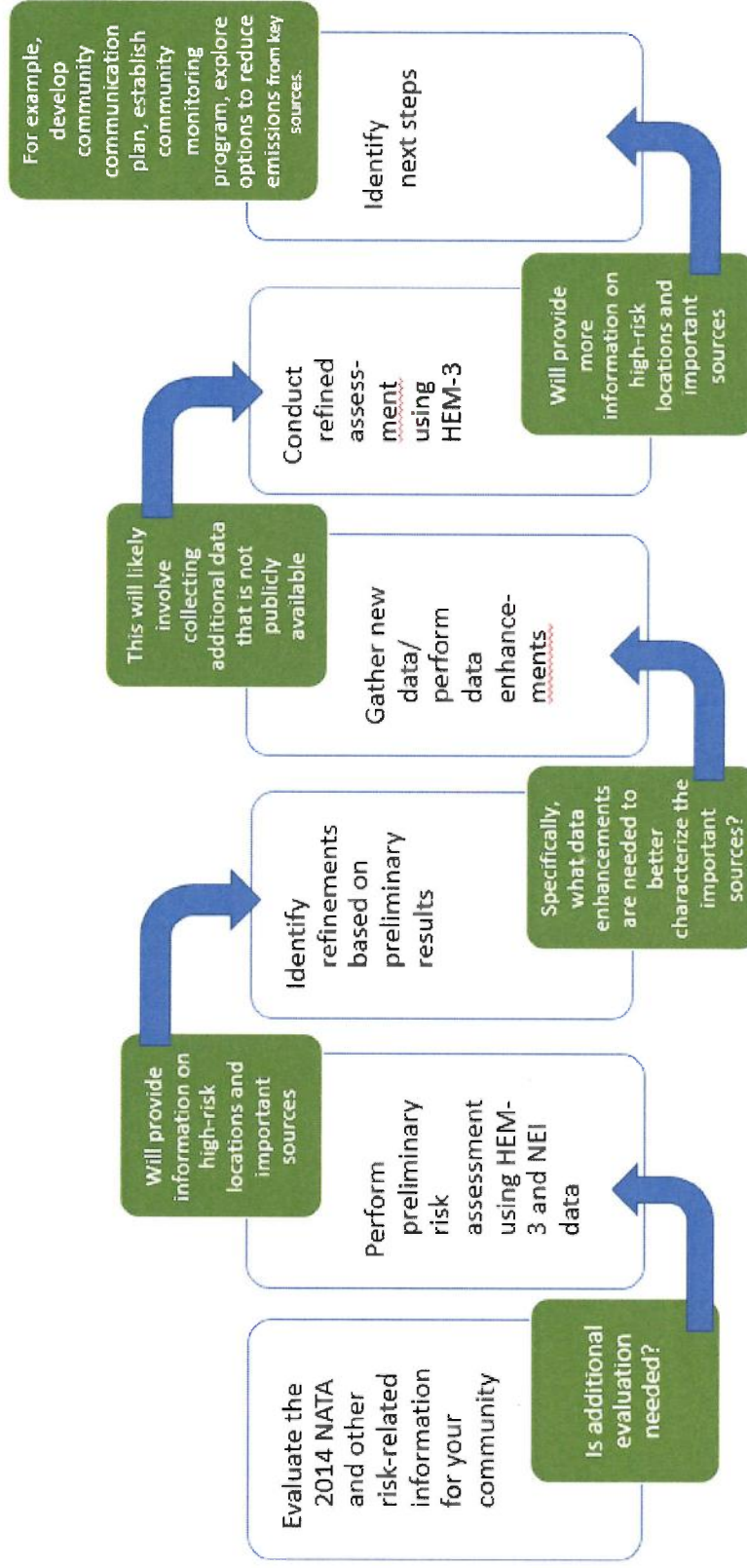
Using HEM-3 to obtain the block-level risks will provide insights into both the maximum risks to which individuals in the community are exposed, as well as the locations of the residences of these individuals. It also provides the opportunity to include special receptors in locations such as schools to predict the risks there. Assessment at the block level also allows a more robust characterization of the number of individuals that are exposed to varying risk levels. Further, the risk impacts on various demographic and socioeconomic populations can be better characterized.

Acute risks are a standard output of HEM-3. HEM-3 compares the short-term estimated concentrations of each air toxic to the applicable toxicological benchmarks that represent an acute health risk.

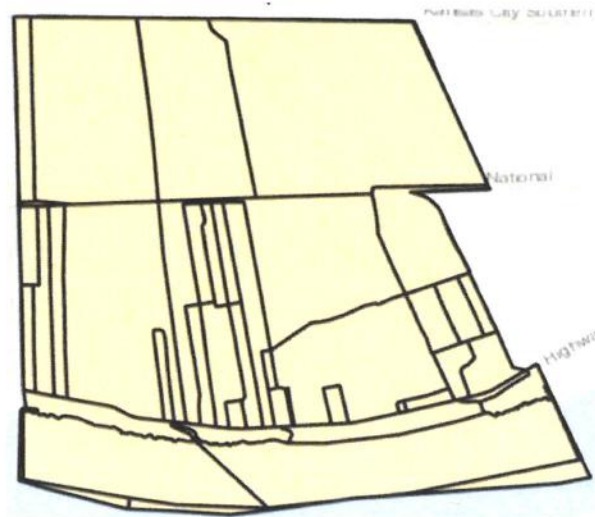
Regarding the sources that contribute to the risk, HEM-3 can provide the specific contribution of every source modeled to the risk at every receptor. Based on our experience, we would recommend that communities exercise caution before basing any significant action on the results of a risk assessment using NEI data. The NEI is an excellent source of information on which to base wide regional and large-scale assessments. However, small errors in point source information (e.g., emission rate, coordinates, stack height, etc.) can make a significant difference in the risk. In addition, for many smaller sources, EPA does not have an exact location in the NATA inventory. They modeled these as nonpoint sources. Emissions from homes, such as wood-burning stoves and fireplaces or solvent emissions, are examples of nonpoint sources. EPA usually inventories nonpoint sources by county, then divides each county into smaller, square "grid cells," then assigns nonpoint emissions to each cell using population or another method that realistically distributes the emissions across the county.<sup>10</sup> They used a similar approach to assign most mobile source emissions. An exception is for airports, which were modeled using their actual locations.

Our suggestion would be to use the results of the quick preliminary assessment to inform areas where the input information can be refined to better estimate the risks. For example, up-to-date emissions information could be obtained from stationary sources, along with confirmation of coordinates and other location information. Additional information could be obtained to refine the modeling to include aspects like the effects of building downwash. For non-stationary sources, identifying specific sources of interest (e.g., a congested road), then specifying their location and configurations and generating more site-specific emissions estimates will improve the risk estimates. Note that some communities may already have better data and want to move ahead initially with a more refined assessment. Or they may already have answers to the key questions of the location and sources of interest. HEM-3, which includes the full capabilities of AERMOD, is also an efficient tool to perform these more refined assessments.

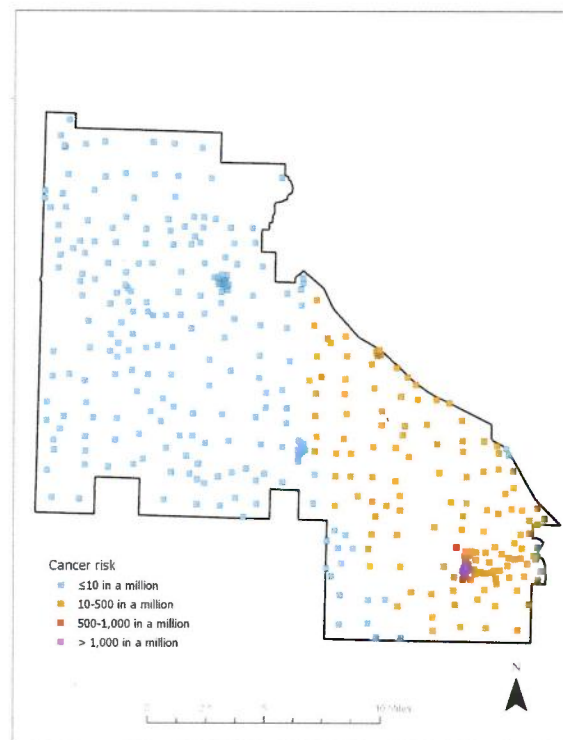
Figure 8. Simplified HEM-3 Based Approach to Assess Community Risks from Air Toxics



**Figure 9. Census Blocks in Tract #22095070800 in St. John the Baptist Parish, Louisiana**



**Figure 10. HEM-3 Cancer Risk Results for One Tract Near an Actual Facility in the Midwest**



After the refined assessment is complete, there are several potential steps that community leaders could take. Communication with the potentially impacted community is vital. Frankly, we would recommend that this engagement begin much earlier in the process than after refined results are obtained, to ensure transparency and to gain the public's trust. Many communities have the desire to perform ambient monitoring. With the availability of high-quality low-cost monitoring techniques on the

rise, this is becoming a more cost-effective aspect of community air toxics programs. The HEM-3 assessments can also inform the best locations for monitoring devices. Another step is to evaluate the options to reduce air toxics emissions, and thus risks. HEM-3 is also used routinely by SC&A for the EPA in evaluating the residual risk to communities, after control measures are put in place.

## SUMMARY

EPA's NATA is a nationwide assessment of the chronic human health risks due to the inhalation of air toxics. It provides basic information about the levels of risks, the number of people exposed to these risks, and the pollutants and source groups that contribute to the risks. In the 2014 NATA, there were over 117 communities in the US for which the NATA reported average cancer risks above the threshold that EPA considers unacceptable. However, the risks reported represent "average" risks across a census tract. The risk within these tracts is most certainly considerably higher nearer the sources. The three air toxics that consistently cause the cancer risks in the communities are ethylene oxide, chloroprene, and formaldehyde. Emissions from stationary (industrial facility) sources emit most air toxics causing the high risks.

HEM-3 is a tool developed by SC&A for EPA to perform assessments of the risks due to the inhalation of air toxics. It is a "one-stop" tool that incorporates EPA's recommended dispersion model AERMOD, meteorological data for stations across the US, census block-level population data for the entire country, and toxicological reference values. HEM-3 can be of great value to communities to help them perform risk assessments with limited resources.

On the horizon is a new version of HEM – HEM Version 4 (HEM-4). HEM-4 is currently under development using state-of-the-science open source code (Python). It will retain all the power and utility of HEM-3 but will run more efficiently using less computer resources. In addition to improvements in user-friendliness, HEM-4 will offer greater flexibility in defining receptor locations, support modeling outside of the U.S., and provide greater visualization tools (e.g., contour maps). Use of the Python programming language will let HEM-4 tap into a huge library of software utilities that can extend the functionality of the model. The first beta-version of HEM-4 is scheduled to be released by the EPA later in 2019.

## ACKNOWLEDGEMENTS

The foundation of our risk assessment work is with EPA's Air Toxics Assessment Group in the Office of Air Quality Planning and Standards. We greatly appreciate the opportunity to work with members of this group including Terri Hollingsworth, Mark Morris, Ted Palma, Kelly Rimer, Chris Sarcony, and Darcie Smith. We also acknowledge Dr. William Battye, who foresaw EPA's risk assessment needs, had the vision for HEM-3, and led its development.



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## APPENDIX A: BREAKDOWN OF POPULATIONS IN HIGH-RISK COMMUNITIES BY VARIOUS SOCIO-ECONOMIC PARAMETERS

Figure A-1. Percentages of Minority Populations

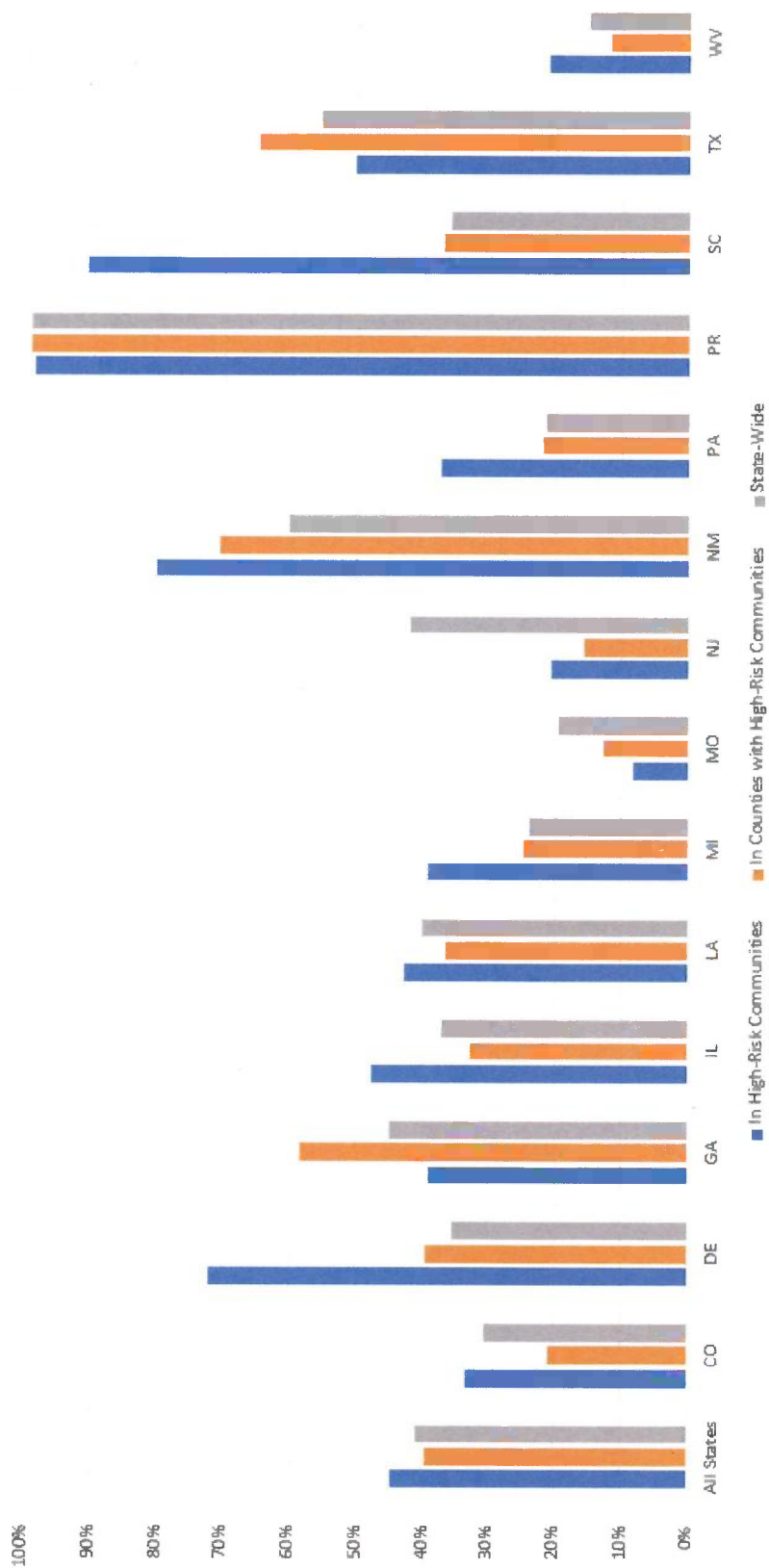


Figure A-2. Percentages of Populations Living in Poverty

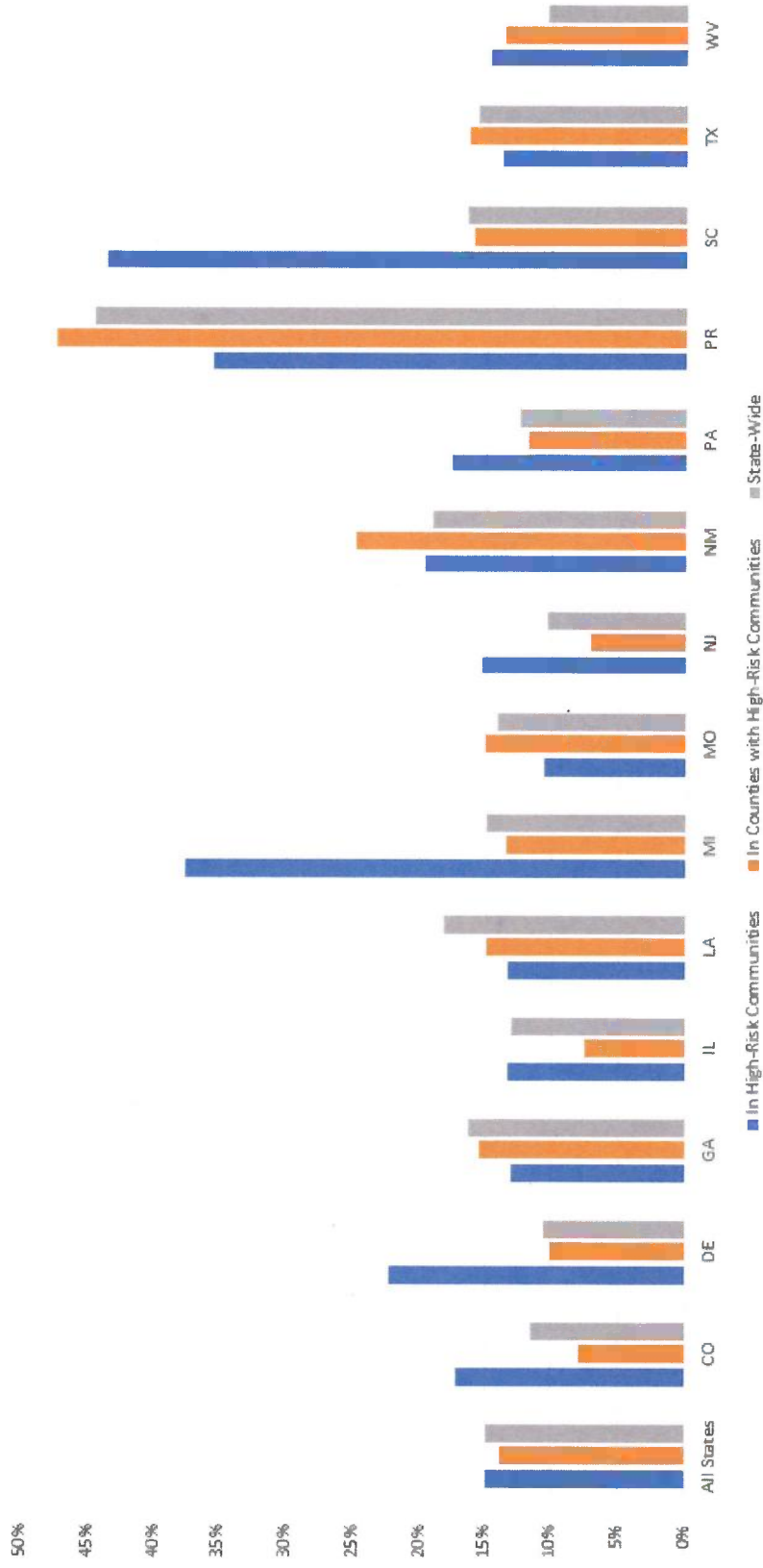




Figure A-3. Percentages of Populations Without a High School Diploma

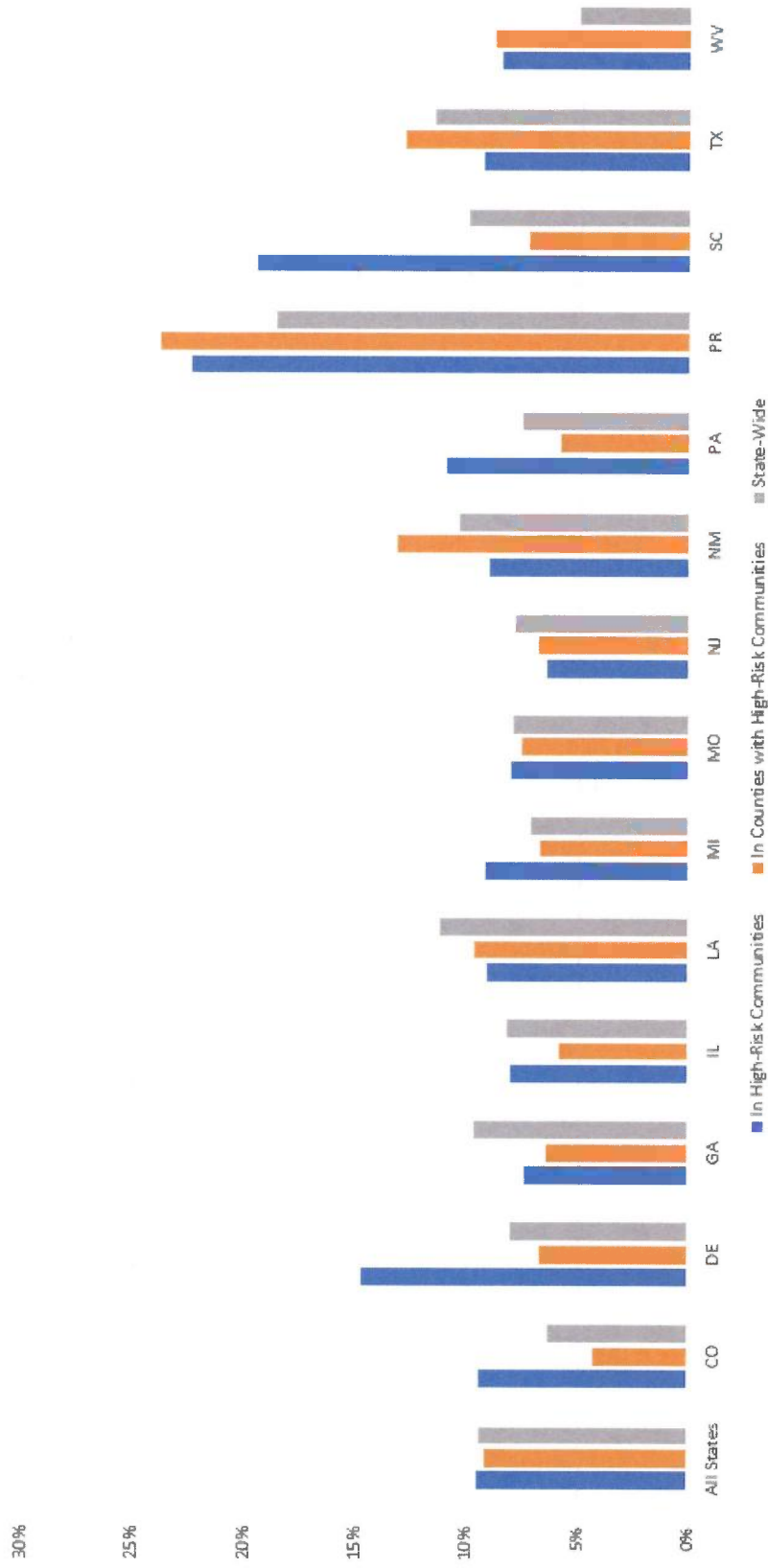


Figure A-4. Percentages of Populations 65 Years Old and Older

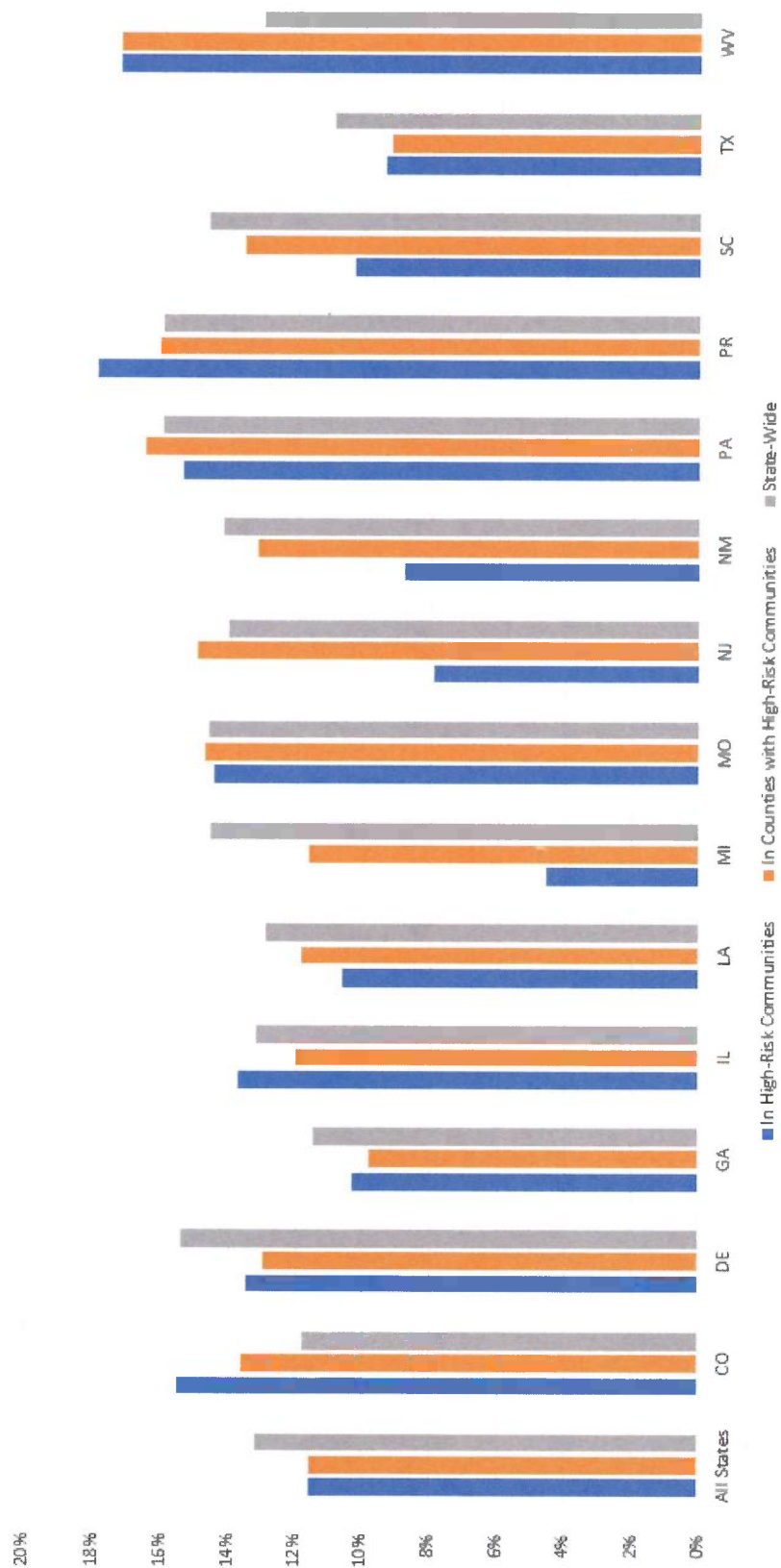
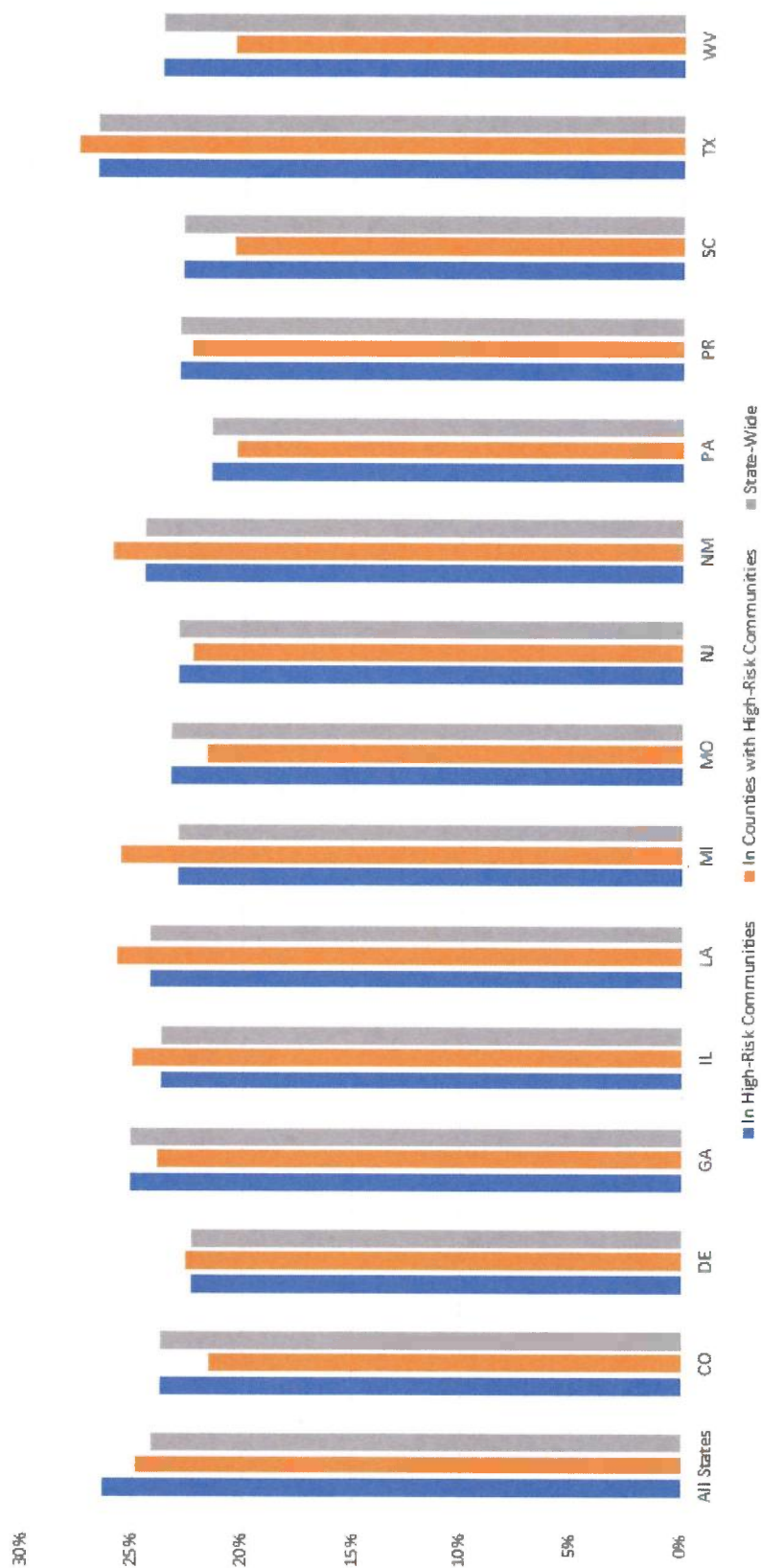


Figure A-5. Percentages of Population 17 Years and Younger





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WINDS OF CHANGE  
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## COMMUNITIES AT RISK FROM AIR TOXICS - DEEPER ANALYSIS OF NATA RESULTS AND TOOL FOR A PATH FORWARD

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